Evidence for Behavioural Nudge Interventions to Reduce Low-Value Care

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Statement of originality

This is to certify that the content of this thesis is my own work. This thesis has not been submitted for any degree or other purposes. I certify that the intellectual content of this thesis is the product of my own work and that all the assistance received in preparing this thesis and sources have been acknowledged.

Gemma Altinger

12 December 2025

Supervisors' statement

As supervisors of Gemma Altinger's doctoral work, we certify that we consider her thesis "Evidence for Behavioural Nudge Interventions to Reduce Low-Value Care" to be suitable for examination.

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I, Gemma Altinger, hereby declare that I have contributed to the design, investigation, project administration, formal analysis, writing manuscript drafts and revisions for each chapter.

Gemma Altinger

12 December 2025

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Adrian Traeger

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Publications and presentations

Parts of the work in this thesis have been published, or are under review in peer-reviewed journals, or were presented at conferences.

Original peer-reviewed publications forming chapters of this thesis

Altinger G, Sharma S, Li Q, et al. *Text message incentives increased patient-reported outcomes survey response in emergency care: SWAT findings.* Journal of Clinical Epidemiology 2025, doi: 10.1016/j.jclinepi.2025.112116 (Chapter Two)

Altinger G, Maher CG, Traeger AC. *Using behavioural economics to improve adherence to home exercise programs.* Journal of Physiotherapy 2024, doi: 10.1016/j.jphys.2024.03.003 (Chapter Three)

Altinger G, Jones, C. Ferreira, GE. Soon, J. Hoffmann, T. Maher, CG. Chang, R. Linder, JE. Traeger, AC. *Effectiveness of clinician-directed default nudges on reducing overuse of tests and treatments in healthcare: a systematic review of randomised controlled trials.* BMJ Quality & Safety 2025, doi: 10.1136/bmjqs-2025-018793 (Chapter Four)

Altinger G, Maher CG, Jones CMP, et al. Multiple Suggested Care Alternatives and Decision-*Making of Primary Care Physicians: A Randomized Clinical Trial.* JAMA Network Open 2025, doi:10.1001/jamanetworkopen.2025.42949 (Chapter Five)

Altinger G, Sharma S, Maher CG, et al. *Behavioural 'nudging' interventions to reduce low-value care for low back pain in the emergency department (NUDG-ED): protocol for a 2×2 factorial, before-after, cluster randomised trial.* BMJ Open 2024, doi: 10.1136/bmjopen-2023-079870 (Chapter Six)

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Original peer-reviewed publications

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Published peer-review conference abstracts

Altinger G, Traeger A57 Using behavioural strategies to communicate risks and benefits of medical interventions: insights from the design of a cluster randomised trial in emergency care BMJ Evidence-Based Medicine 2023;28:A28.

Altinger G, Sharma S, Maher CG, et al 062 NUDG-ED: a 2x2 factorial, before-after, cluster randomised trial using behavioural nudges to reduce overdiagnosis and overtreatment of back pain in the emergency department. BMJ Evidence-Based Medicine 2025;30:A32.

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Wyk AV, **Altinger G,** Sharma S, et al 078 Clinician experiences of behaviourally informed interventions to reduce overdiagnosis and overtreatment of back pain in Australian emergency departments. A qualitative study. BMJ Evidence-Based Medicine 2025;30:A39.

Peer-reviewed scientific conference presentations – oral presentations

International:

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Invited presentations

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Academic appointments

2025 - Current: Preventing Overdiagnosis International Early Career Researcher Committee

2025 - Current: Co-Chair, Consumer Engagement Portfolio Committee, Institute for Musculoskeletal Health

2023 - 2024: Member, Consumer Engagement Portfolio Committee, Institute for Musculoskeletal Health

Scholarly awards and prizes

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Abstract

Introduction

Low-value care, defined as tests and treatments that are of limited benefit, inappropriate, or harmful, poses a significant challenge to the quality, safety, and sustainability of healthcare systems worldwide. Estimates suggest that approximately 40% of all healthcare practices may be low-value care. Low back pain is a leading cause of disability globally and is a major driver of low-value care, including unnecessary diagnostic imaging and opioid prescribing, particularly in emergency department settings. Traditional de-implementation strategies, such as educational campaigns, are resource intensive and have had limited success in reducing low-value care. Interventions informed by behavioural economics, commonly referred to as nudges, have therefore been proposed as a potentially scalable approach to reducing low-value care, although their effectiveness remains uncertain.

Aims

The primary aim of this thesis was to evaluate the evidence on the effectiveness of nudges in reducing low-value care. The specific objectives of this thesis were to: 1) evaluate the impact of text message-based nudge interventions on patient reported outcome survey response rates in routine emergency care settings (Chapter Two); 2) review theory and evidence to identify behavioural economic techniques physiotherapist could implement to improve patient adherence to home exercise programs (Chapter Three); 3) evaluate the evidence on clinician-directed default nudges to reduce overuse of tests and treatments (Chapter Four); 4) evaluate the effect of the number of suggested care alternatives in nudges on low-value care decisions by primary care physicians (Chapter Five); and 5) evaluate the effect of patient- and clinician-

directed nudges on reducing low-value care for patients with low back pain in emergency care settings.

Methods

The thesis used multiple research methods to evaluate behavioural economics and nudge interventions in healthcare. Chapter Two utilised a study within a trial design to evaluate the effect of text message-based nudges on patient reported outcome survey response rates among patients with back pain discharged from Sydney emergency departments. Chapter Three used a narrative review to propose behavioural economic techniques for physiotherapists to improve patient adherence to home exercise programs. Chapter Four used rigorous systematic review methods to synthesise and critically evaluate the efficacy of clinician-directed default nudges on overuse of tests and treatments. Chapter Five used randomised controlled trial methods to evaluate the effect of the number of preferred care alternatives in suggested alternative nudges on primary care physician care decisions for two clinical scenarios commonly seen in primary care. Chapters Six and Seven used factorial cluster randomised controlled trial methods to evaluate the effect of patient- and clinician-directed nudges on low-value care for patients with back pain in eight Sydney emergency departments.

Results

This thesis provides rigorous evidence on the effects of nudges on low-value care. Nudge effects varied substantially by nudge type, targeted behaviour, patient population, and clinical context. Chapter Two's nested randomised controlled trial showed that text message nudges increased patient-reported outcome survey response rates. A prize-draw incentive increased overall response rates, while pro-social framing appeared to enhance participation among disadvantaged patients. Chapter Three provided physiotherapists with behavioural economic

strategies that could improve adherence to home exercise programs. Chapter Four's systematic review found low to moderate-certainty evidence that default nudges can substantially reduce overuse of tests and treatments, although an observed increase in overuse in one study highlights the need for clinically appropriate design and careful evaluation of unintended consequences. Chapter Five showed that suggested-alternative nudges offering between two to four preferred care alternatives reduced primary care physicians' selection of low-value care. In contrast, Chapter Six and Seven's 2x2 factorial cluster randomised controlled trial, NUDG-ED, found that neither clinician- nor patient-directed nudges reduced low-value imaging or opioid prescribing at discharge for patients with low back pain in emergency departments.

Conclusion

This thesis provides robust evidence on both the potential for and limitations of nudges to reduce low value care. Nudges appear to be a feasible de-implementation strategy in routine settings, but their effects depend strongly on clinical context and intervention design. Nudge effects may be moderated by factors such as the costs of changing behaviour, perceived risks of harm from de-implementation, and the timing of consequences. As nudges become more widely used in healthcare, rigorous evaluation, monitoring of unintended effects, and inclusion of patient centred outcomes are essential.

CHAPTER ONE: Introduction

Chapter One provides a background on topics relevant to this thesis, including low-value care, low back pain and de-implementation of low-value care for patients with low back pain. The introduction is not intended as a systematic review of the literature but rather offers contextual information and evidence to orient the reader to the research area and highlight gaps in evidence that underpin the thesis aims and objectives.

1.1 Low-value care undermines the quality, safety and sustainability of healthcare

1.1.1 Low-value care is a global challenge

Low-value care presents a major challenge to international healthcare systems. Low-value care refers to tests and treatments that provide little or no clinical benefit and can cause harm.[1] With little-to-no clinical benefit, low-value care exposes patients to unnecessary risks and wastes scarce healthcare resources.[2] As such, examining the burden of low-value care has been identified as an priority internationally.[3] Low-value care occurs in many high-income countries including the United States, the United Kingdom, Canada, Japan and Australia.[1] There is growing evidence that low-value care is also an issue in low and middle income countries including Brazil, India and China.[4] One well-cited estimate based on large empirical studies from the United States, the United Kingdom, Australia and the Organisation for Economic Co-operation and Development suggests that approximately 40% of all healthcare practices are either low-value (30%) or harmful (10%).[5]

The prevalence of low-value tests and treatments varies widely across countries, health conditions, and clinical interventions. For example, estimates for low-value use of antibiotics for uncomplicated upper respiratory tract infections ranged from 2% to 89% of patients in the United States,[6] and from 37% to 47% in China.[7] Antibiotic use for viral infections is one of the most well-recognised examples of low-value care, particularly given the growing awareness of its inefficacy for viruses and contribution to antimicrobial resistance.[8] Other well-known examples of low-value care include endoscopy for patients at low risk of cancer, preoperative tests for low-risk patients, and imaging for non-specific low back pain.[1]

Overuse of low-value care is costly. In the United States alone, a 2019 review of systematic reviews estimated that low-value care costs between $75.7 billion to $101.2 billion annually across both private and public settings (based on n = 11 estimates across healthcare settings).[9]

Of this spending, the authors estimated that $USD12.8 billion to $USD28.6 billion could potentially be saved annually by reducing low-value care such as cancer screening in older adults, routine cardiac stress testing and unnecessary imaging for patients with low back pain.[9] In Australia, low-value care in public hospitals is estimated to cost between $A49.9 million and $A99.3 million per year in inpatient expenditure.[10] A 2024 Australian analysis suggested that supervised withdrawal or deprescribing of unnecessary medicines in older adults alone could save $A1–$16 million per year.[11] Even the lower bound of these estimates suggests a significant saving to the health system.

Low-value care is also associated with substantial opportunity costs. Unnecessary care consumes clinician time, healthcare budgets, and system capacity that could otherwise support high-value, evidence-based care. The Australian Care Track study, which assessed the appropriateness of care for 22 common conditions in primary care, revealed a significant gap between care recommended in guidelines and actual practice.[12] They found that in a representative population sample (n = 1,154; 35,573 encounters), appropriate care was only provided in 57% (95% CI: 54% to 60%) of encounters.[12] Notably, low back pain emerged as the most common presentation, accounting for nearly one-fifth (19%; 6,588 of 35,573 encounters) of all assessed visits.[13] Only 54% (840 of 1,557) of patients with low back pain received recommended care by primary care physicians.[13]

1.2 Patients with low back pain often do not receive the right care

1.2.1 Low back pain is common and costly

Low back pain affects millions of people worldwide. It is the leading cause of years lived with disability globally.[14] In 2020, over 619 million people globally experienced low back pain.[15] With a growing and aging population, prevalence is estimated to increase to 842 million people by 2050.[15] In Australia, low back pain is highly prevalent, affecting an estimated 67.6%

(95% CI: 65.5% to 69.7%) of adults within a 12-month period and most people will experience low back pain at some point in their lives (79.2%; 95% CI: 77.3% to 81.0%).[16]

The economic burden associated with low back pain is substantial. Back pain costs the Australian health system $4 billion annually.[17] Additionally, a recent economic model estimated that over 3 million Australians were projected to have long-term back problems by 2033, with indirect costs from productivity losses and premature workforce exit could exceed $638 billion over the next decade.[18] Given the high prevalence and costs, improving the quality of care is essential for reducing the burden of low back pain for patients and society more broadly.[19]

1.2.2 Conservative care is recommended as first-line treatment for low back pain

Internationally, guidelines recommend reassurance, education, heat, physical and psychological therapies for most patients in primary care settings.[20] This is because most patients (approximately 99%) in primary care do not have a serious underlying spinal pathology that requires specific medical or surgical intervention.[21] Where analgesics are warranted, non-steroidal anti-inflammatory drugs are recommended.[20] Despite clear guideline recommendations, many patients with low back pain are not receiving recommended care. A systematic review of 26 studies examining health record data (n = 194,388 patients) from Australia, the United States and the United Kingdom found that less than one quarter received reassurance and education, less than one fifth were advised to exercise, and less than one third were referred for physiotherapy.[22]

1.2.3 Diagnostic imaging is often low-value care for patients with low back pain

Diagnostic imaging for back pain is only appropriate when serious underlying spinal pathology is suspected. Clinicians are expected to look for signs of fracture, infection, systemic illness

and/or neurological compromise that warrant further diagnostic workup.[23] Serious spinal pathology such as vertebral fracture, septic discitis or spinal cord compromise is rare, diagnosed in fewer than 1% of back pain cases in primary care,[21] though it is more common in emergency department settings (~3-5% of encounters).[24] Non-spinal pathologies can also present as back pain. Conditions such as renal colic or urinary tract infections often present to emergency care as back pain, which further complicates the diagnostic process.[25] In one study, 27% (8,478 of 31,168) of back pain presentations were attributable to non-spinal pathology.[25] This complexity presents a challenge to clinicians deciding whether diagnostic work-up (e.g. imaging, pathology testing) is indicated, particularly in emergency settings.

Diagnostic imaging is frequently overused for patients with low back pain. For non-specific low back pain without suspicion of serious spinal pathology, imaging offers little value in identifying the underlying cause or in guiding treatment plans.[26] Unnecessary imaging can also cause harm. In primary care, it may detect incidental findings such as a "disc bulge," which are common in asymptomatic individuals and offer little clinical or diagnostic value.[27] However, diagnostic labels contained in imaging reports can increase patient perceptions of seriousness and the perceived need for surgery.[28] In emergency care, the downstream effects of unnecessary imaging may be less important as patients often do not have access to their imaging reports. However, imaging can extend the length of stay for patients with low back pain, exacerbating issues of overcrowding and delays in care in the emergency department.[29-31] Delays in care for patients with high-urgency conditions can lead to worse health outcomes and serious adverse events.[32] Despite this, approximately one in four patients who seek care for low back pain receive diagnostic imaging across primary and emergency care settings.[33] A 2025 analysis of Medicare spending in the United States ranked imaging for low back pain among the five most common low-value services, alongside imaging for plantar fasciitis, imaging for headache and vertebroplasty.[34]

Despite clear guidelines recommending against the use of imaging for patients with suspected non-specific low back pain, low-value imaging still occurs. A 2021 chart-review study applying clinical guideline criteria found that 36% (57 of 158) of spinal imaging tests in the emergency department were provided without clinical indications and were therefore considered low-value.[35] At the same time, imaging was also underused in some patients who needed it. 4.3% (28 of 649 encounters) of low back pain encounters did not receive appropriate imaging despite being clinically indicated.[35] These findings highlight a persistent gap between guideline recommendations and clinical practice, demonstrating that both overuse and underuse can contribute to suboptimal care quality and safety.

1.2.4 Opioid analgesics are low-value care for most patients with low back pain

Opioid analgesics are widely regarded as low-value care for low back pain due to their lack of benefit and risks of harm. A 2023 Australian randomised controlled trial found that adding opioids (oxycodone-naloxone, up to 20 mg/day) to usual care for acute low back pain provided no significant difference in pain relief at 6 weeks compared with a placebo (mean pain score 2.78 in opioid group vs. 2.25 in the placebo group; adjusted difference 0.53; 95% CI -0.00 to 1.07; P = 0.051; n = 347).[36] Short-term harms can include nausea, dizziness, vomiting and constipation.[37] Longer-term harms can include dependence, overdose and death.[37] In Australia, opioid poisonings and overdoses lead to nearly 150 hospitalisations, 14 emergency department visits and 3 deaths every day.[37] In 2016, opioids were responsible for 62% of all drug-induced deaths in Australia, and between 2007 and 2016, opioid related deaths increased from 2.9 deaths per 100,000 people to 4.7 deaths per 100,000 people.[37] Short term opioid use, even in emergency care settings, can lead to long-term use and increase the risk of harm. A systematic review and meta-analysis of 72 studies estimated that 7% of opioid-naive patients with musculoskeletal pain who received an opioid in the emergency department continued using

opioids at 3 to 12 months after discharge.[38] Few trials have evaluated the efficacy of opioids administered in the emergency department, but the clear and well-documented risks of harm suggest that, on balance, opioids likely do more harm than good for low back pain.[39] Reducing opioid initiation in emergency care therefore has substantial potential to mitigate long-term dependence and opioid-related harms.

Despite clear guideline recommendations to avoid them, opioids continue to be frequently prescribed for low back pain across clinical settings. Internationally, up to 31% (6,619 of 21,350) of patients with low back pain received an opioid in primary care and up to 61% (2,499 of 4,097) in emergency care.[22] In Australia, approximately 19.6% (334 of 1,706) of patients with acute low back pain received an opioid prescription in primary care, and 69.9% were administered an opioid in emergency care.[40] These findings highlight a persistent gap between guideline recommendations and clinical practice.

1.3 Reducing low-value care is essential for improving healthcare

There is clear evidence that low-value care for low back pain is prevalent across both primary and emergency care settings. Addressing this problem presents a different challenge to increasing use of effective care. Although practice can change slowly in response to new evidence, stopping established ineffective practices in response tends to be much slower.[41] The following sections examine existing approaches to reducing low-value care.

1.3.1 The drivers of low-value care are complex and interconnected

Low-value care is driven by a diverse set of system-, clinician-, and patient-level factors. Conceptual frameworks such as the Right Care Series in *Lancet* and the Overdiagnosis Series in *BMJ* have mapped a complex network of multi-level drivers contributing to low-value care.[42-44] These can include both external factors (regulation, incentives, accessibility of care

options and culture) and internal factors (knowledge, beliefs, habits and emotions of clinicians and patients) that interact to shape both the demand for, and supply of, low-value care.[42-44]

1.3.2 De-implementation strategies can reduce, replace, remove or restrict low-value care

To mitigate harm and improve healthcare quality, low-value practices must be de-implemented from routine care. Unlike implementation, de-implementation presents distinct challenges because targeted practices are often familiar, expected, and embedded in everyday clinical workflows.[45] De-implementation strategies, which are typically different from implementation strategies,[46] aim to deliberately reduce, replace, remove, or restrict the provision of low-value care. [47] A range of approaches has been employed, including guideline updates, funding reforms, population-level restrictions, public health campaigns, and knowledge translation interventions.[48] However, the appropriateness of any strategy depends on the characteristics of the low-value practice, the patient population, the clinicians involved, and the healthcare setting.[49]

Strategies that fail to consider the unique characteristics of targeted low-value practices may do as much harm as the low-value care they seek to reduce. This was demonstrated by the population-level policies introduced in response to rising rates of opioid-related harms. Governments, including in the United States and Australia, introduced population-level opioid control policies and programs that restricted or monitored opioid prescribing with the aim of reducing opioid-related harms.[50] While these policies offered a scalable approach, in practice, their rigid application often resulted in premature opioid tapering and undertreatment of patients with chronic pain conditions.[50] Premature tapering contributes to worse pain, mental health events, increased illicit drug use, and overdose.[51,52] These policies overlooked the complexity of pain and undermined principles of safe deprescribing which include working with patients to develop personalised, goal based deprescribing plans to gradually taper opioids

with ongoing, multidisciplinary support.[53] Similarly, any policy to restrict imaging services for patients with low back pain could lead to substantial harms to patients if serious pathologies are missed.

1.3.3 Patient-centred approaches are essential for reducing low-value care for low back pain

Given the complexity and heterogeneity of low back pain, targeting clinicians and patients directly to reduce low-value care may be more appropriate than broad policy measures. Targeted strategies may better align with patient-centred care principles and help mitigate harms arising when individual patient factors are overlooked. Furthermore, de-implementation strategies that aim to *reduce* or *replace* low-value practices, rather than *remove* or *restrict* care, may be more appropriate for de-implementation of low-value practices for low back pain.[49] As such, this thesis focuses on clinician- and patient-directed strategies implemented at the point of care. The following sections review the evidence on these approaches.

1.4 Traditional de-implementation approaches have limited impact for low back pain

1.4.1 Traditional approaches have not reduced low-value care in primary care

The evidence for clinician-directed strategies for reducing low-value care in primary care is limited. A 2015 systematic review reported that clinician education (including face-to-face education and guideline dissemination) had no significant effect on imaging rates for low back pain (3 high-quality trials).[54] Notably none of those trials measured appropriateness to determine if imaging could be considered low-value care. Similarly, a 2022 systematic review and meta-analysis found low certainty evidence that clinician education, alone or combined with other interventions, did not improve guideline-concordant prescribing of medicines for patients with low back pain (OR: 0.94; 95% CI: 0.77 to 1.16; 5 studies [3 in primary care, 1 in emergency care and 1 in physiotherapy]; low certainty evidence).[55] Collectively, this suggests

that clinician-directed education alone has to date been largely ineffective at reducing low-value care for low back pain across healthcare settings.

Some trials to address imaging in primary care have combined clinician- and patient-directed components. A 2021 cluster randomised controlled trial provided primary care clinicians with a 30-minute training session and a patient-education booklet that clinicians can provide to patients about the appropriateness of imaging for low back pain.[56] The intervention did not significantly reduce overall rates of lumbar imaging (imaging rate = 16.7% [31 of 186 patients] in the control group vs. 10.8% [19 of 179 patients] in the intervention group received imaging referrals; OR 0.57; 95% CI: 0.27 to 1.22).[56] However, the study design may have had limited patient exposure, as some individuals may never have received the educational resources or fully engaged with them. Consequently, effective interventions to reduce low-value imaging in primary care remains a significant research gap.

1.4.2 Traditional approaches have had mixed effects on low-value care in emergency care

In emergency care settings, low certainty evidence suggests that traditional education strategies have limited impact on imaging. A 2024 systematic review found very low certainty evidence that clinician- and patient-directed educational interventions did not significantly reduce overall lumbar imaging in the emergency department (OR 0.85; 95% CI: 0.64 to 1.12; I^2 = 66%; 10 studies including observational designs; n = 9,804 patients; very low certainty evidence).[57] While no overall effect was observed, a subgroup meta-analysis found that in sites with high baseline imaging rates (≥36%), interventions reduced overall imaging (OR 0.60; 95% CI 0.39–0.93; three studies), suggesting baseline imaging may moderate de-implementation effects.[57] However, the small number of mostly observational studies, heterogeneous effects, and lack of measures of imaging appropriateness limit the clinical relevance and certainty of these findings, highlighting the need for more rigorous research.

In contrast to interventions targeting imaging, low certainty evidence suggests that traditional education strategies may reduce opioid use for patients with low back pain in the emergency department. The same 2024 review found that clinician- and patient-directed education, alone or combined with other strategies, was associated with reduced opioid prescribing (OR 0.65; 95% CI: 0.55 to 0.75; $I^2 = 0\%$; 6 studies including observational designs; n = 7,361; low certainty evidence).[57] However, combining multiple education and non-education strategies (including guideline dissemination, education seminars, educational materials, clinical champions and embedded emergency department advanced physiotherapists) into a single estimate made it difficult to determine which interventions were most effective.

1.4.3 Evidence highlights key gaps in traditional methods of reducing low-value care

Three key limitations emerge from the evidence on clinician- and patient-directed educational strategies to reduce low-value care for low back pain. First, many de-implementation studies rely on overall rates of tests or prescriptions without assessing clinical appropriateness to confirm that the care was indeed low-value care. This limitation is particularly important in low back pain. For example, a reduction in overall imaging rates may reflect a reduction in unnecessary imaging or also a reduction in clinically indicated imaging. Second, few studies have collected patient reported outcomes. These data are essential to ensure de-implementation strategies improve the quality of care, do not reduce necessary care or adversely affect patient outcomes.[58] Finally, traditional educational strategies are resource-intensive, costly to implement, and require ongoing investment to achieve sustained reductions in settings where clinical staff rotate.[59] Additionally, these approaches can increase demands and pressure on clinicians.[60] Such limitations pose a significant barrier to scalability, particularly in resource-constrained, non-metropolitan, or high-volume settings such as emergency departments.[61]

These limitations highlight the need for novel, scalable strategies to reduce low-value care for patients with back pain across healthcare settings. Indeed, a 2022 systematic scoping review of 227 trials targeting the de-implementation of various low-value practices across settings reported similar limitations in the evidence base for traditional educational strategies.[62] The review emphasised the need to design approaches that not only achieve reductions in research settings but can also be adopted in real-world practice to deliver meaningful improvements in care. Behavioural economics has been suggested as an approach to addressing these limitations of scalability, resource intensity, and real-world adoption of de-implementation strategies.[59,63]

1.5 Behavioural 'nudge' strategies offer a scalable approach to reducing low-value care

1.5.1 Nudges have gained popularity as a behaviour change strategy

Behavioural economics draws on economics, psychology, sociology, and neuroscience to understand decision-making. Early economists examined how culture, politics, relationships, regulation, technology, and systems shape individual and societal behaviour,[64] with empirical research on decision-making emerging in the 1940s.[65] Behavioural economics is now most commonly recognised for its theories of cognitive biases and "nudge" strategies, offering an intuitive approach to understanding and influencing behaviour.[66] Popularised in 2008 by Thaler and Sunstein's release of their book, *Nudge: Improving Decisions About Health, Wealth, and Happiness,*[67] nudges are subtle modifications to the decision environment designed to make preferred actions easier, more attractive, or simpler.[66] Importantly, nudges do not coerce or restrict decision-makers, preserving their autonomy.[68] By their nature, nudges are intended to be light-touch and low-cost interventions that can be implemented at scale. They have been widely adopted by policymakers worldwide, with the first "nudge unit" established by the British Prime Minister in 2010.[69] By 2024, over 600 nudge units had been created in public and private organisations, including in Australia.[69] Since then, nudges have been

applied across diverse domains, including the promotion of healthy eating, improvement of tax compliance, and reduction of energy consumption.[70]

1.5.2 Nudges are increasingly being used in healthcare settings

Over the last decade, nudges have been tested in clinical care settings to improve clinician decision-making. In 2016, Penn Medicine established the first nudge unit to test nudges within clinical care settings.[71] They have reported evidence suggesting nudges increase generic medicine prescribing, facilitate appropriate specialist referrals,[71] and encourage discussions about end-of-life options.[72] While promising, they have not been as widely investigated as traditional approaches to reducing low value care.

As a light-touch, scalable intervention that does not restrict choice, nudges may offer a valuable strategy for targeting both clinicians and patients to reduce low-value care and enhance the quality of care across settings. The following section describe opportunities and evidence for nudge interventions across five key areas: nudges to improve the collection of patient reported outcomes; behavioural economic strategies to improve adherence to recommended care; 'default nudges' to reduce overuse of low-value care; optimising the design of clinical decision supports with 'suggested alternative nudges' to reduce low-value care; and clinician- and patient-directed nudges targeting low-value imaging and opioids for patients with low back pain in the emergency department.

1.6 This thesis examines the evidence for nudges in healthcare settings

1.6.1 Nudges could increase patient reported outcome response rates in routine care

Without patient reported outcome data, it is not possible to determine whether patients genuinely benefit from de-implementation strategies or whether unintended harm may be occurring. Despite this, patient reported outcomes are rarely collected or achieve very low

response rates in pragmatic trials conducted in routine care.[73] In a systematic review based in emergency care, of the 28 studies (mostly observational designs) evaluating interventions to reduce low-value care for low back pain, only eight reported patient reported outcomes.[57] Collecting patient reported outcomes is particularly challenging in emergency departments, where patients with back pain often experience high levels of pain and distress.[74]

Nudges leveraging extrinsic and intrinsic motivation could address the challenge of collecting patient-reported outcome data in routine care. A Cochrane meta-analysis of 16 trials found that strategies leveraging extrinsic motivation, such as through prize draws and gift cards, increased survey response rates compared with a control (OR 1.60; 95% CI: 1.25 to 2.05; I^2 = 93%; n = 38,901 participants).[75] Strategies leveraging intrinsic motivation through pro-social framing, where benefits to others are emphasised,[76] also improved response rates (OR 1.38; 95% CI: 1.07 to 1.78; I^2 = 41%).[75] However, significant heterogeneity in effects was observed across studies, and no interventions were embedded in routine care settings.

Embedding these nudge techniques within patient survey invitations may provide a feasible and effective means of improving response rates. This would strengthen the quality of evidence generated in pragmatic trials to reduce low value care. However, to my knowledge, their application has not yet been tested in routine care settings.

To address this gap, Chapter Two presents the results from a nested study within a trial, that evaluated whether text-message based nudge interventions (a prize-draw incentive and pro-social framing) could increase response rates to a patient reported outcome survey in the emergency department.

1.6.2 Behavioural economic strategies could improve adherence to recommended care

Improving adherence to recommended care may indirectly reduce the use of low-value interventions. For low back pain, physical therapy and exercise are commonly recommended for both treatment and prevention.[19] Moderate-quality evidence suggests that exercise may help prevent recurrence of back pain.[77] However adherence to exercise prescriptions could be as low as 30%.[78] Improving adherence to guideline recommended care such as an exercise program remains important for optimising patient outcomes.[79] To my knowledge, no study has explored the potential for behavioural economic techniques to improve patient adherence to effective care programs.

This gap will be addressed by Chapter Three, which critically evaluates theory and evidence to propose behavioural economic techniques that physiotherapists can implement in daily practice to improve patient adherence to home exercise programs.

1.6.3 Default nudges could reduce overuse of low-value care

Default nudges may reduce the overuse of low-value care by altering settings within electronic order forms for tests and treatments. A default nudge pre-selects a preferred option, which is delivered unless the clinician actively chooses an alternative.[80] In the context of low-value care for low back pain, default nudges can set lower quantities, doses, or frequencies for interventions that carry unnecessary risk such as opioids. For example, pre-selecting a smaller number of opioid tablets for patients with low back pain could theoretically reduce overuse. Unless clinicians have strong preferences, a default within the electronic health system may be interpreted as the recommended quantity.[81] Default nudges offer a pragmatic way to reduce overuse and minimise harms from overuse.

Default nudges have been identified as a potentially promising approach for influencing clinical decision-making. Systematic reviews examining the effects of various nudge types have suggested that default nudges may improve clinician behaviour across domains such as medicine prescribing, and routine pathology and imaging testing.[82-85] However, previous reviews combined observational designs and studies addressing a range of clinician behaviours, including underuse of recommended care and overuse of low-value care. Additionally, previous reviews applied synthesis methods at risk of bias, such as narrative syntheses and vote-counting based on statistical significance.[86] These limitations can lead to misleading conclusions, provide no indication of effect magnitude or variance, and make it difficult to isolate the impact of default nudges on the use of low-value care.[87]

To date, no review has used rigorous synthesis techniques, generated standardised effects on low-value care, or focused on a single nudge type. These gaps highlight the need for high-quality syntheses to accurately assess the effectiveness of default nudges on reducing low-value care.

To address this research gap, Chapter Four presents the first systematic review to synthesise and critically evaluate evidence on clinician-directed default nudges and their impact on reducing overuse of tests and treatments, using rigorous synthesis methods.

1.6.4 Suggested alternative nudges could reduce low-value care

Suggested alternative nudges embedded within clinical decision support systems may reduce low-value care by offering clinicians recommended substitutes at the point of care. Clinical decision supports can disrupt established ordering habits and remind clinicians of guideline recommendations.[59] Suggested alternative nudges extend this approach by presenting preferred care options to replace low-value practices.[88] For example, rather than simply alerting

clinicians that opioid analgesics are not recommended for patients with non-specific low back pain, a suggested alternative nudge could provide recommended non-steroidal anti-inflammatory drugs to support clinicians to make more guideline concordant decisions.

Although suggested alternative nudges may help clinicians substitute recommended care for low-value practices, current evidence remains limited and uncertain. A large randomised controlled trial in primary care (n = 14,753 encounters) found no effect of a suggested alternative nudge on low-value antibiotic prescribing.[89] One possible explanation is choice overload, as clinicians were presented with 15 treatment alternatives.[90] Classic experimental work by Redelmeier and Shafir (1995)[91] examined the effect of multiple care options on primary care physicians decision-making. They found that physicians presented with two care alternatives, instead of just one, were more likely to remain with the existing management plan rather than opting for an alternative. They reported that offering two alternatives instead of one increased the likelihood that physicians would stick with the existing management plan, suggesting that even minimal increases in choice can produce choice overload. However, a later study failed to replicate this effect,[92] leaving uncertainty about whether a suggested alternative nudge is a worthwhile strategy for reducing low-value care.

These uncertainties have important implications for designing clinician-directed nudges and alert systems. Presenting too many alternatives may cause choice overload, prompting clinicians to continue low-value practices. Conversely, restricting the number of alternatives could limit access to potentially beneficial options, risking suboptimal care.[93]

To address this critical gap, Chapter Five presents findings from a randomised trial examining the effect of the number of care alternatives in suggested alternative nudges on primary care physician decisions to remain with a low-value care option or replace it with a preferred alternative.

1.6.5 Nudges could reduce low-value care for patients with low back pain in emergency care

Clinician-directed nudges embedded in clinical decision support systems may help reduce low-value imaging and opioid prescribing, though the evidence is indirect. A meta-analysis of 122 trials found that clinician-directed decision support tools increased adherence to recommended care across diverse care settings and conditions by 5.8% (95% CI: 4.0% to 7.6%; I^2=76%; n = 1,203,053 patients).[94] Considerable heterogeneity across trials indicated variation in effectiveness by setting, intervention design, and clinical context. Most trials targeted underuse, were conducted in the United States, and none focused on patients with low back pain. Thus, the effectiveness and safety of clinician-directed nudge interventions for reducing low-value back pain care in the emergency department remains uncertain.

Patient-directed nudges, such as behaviourally informed messages on waiting room posters, may adjust patient expectations and reduce demand for low-value care. These nudges can correct common misperceptions about the necessity or benefit of certain tests or treatments. In a high-quality primary care trial (n = 954), nudge posters reduced inappropriate antibiotic prescribing from 52.7% (95% CI: 44.2–61.9%) in the control group to 33.7% (95% CI: 25.1–43.1%) in the nudge group.[95] However, these effects may not generalise across other settings or low-value practices. To my knowledge, no study has evaluated whether patient-directed nudges can reduce low-value care for patients with back pain in the emergency department.

Clinician- and patient-directed nudges could offer several advantages. They are low-cost and scalable, making them feasible in under-resourced or high-volume settings such as emergency departments.[62] Their integration into routine workflows also increases the likelihood of sustained use beyond the trial period.[96] However, high-quality evidence remains limited, and important gaps remain regarding their effects on care quality and patient outcomes. Given the

complexity of reducing low-value care for patients with low back pain, particularly in emergency settings, direct evidence for tailored, context-specific nudges is essential.

To address this critical gap, Chapter Six describes the design and behavioural economic rationale for the first 2×2 factorial, open-label, cluster randomised controlled trial examining the effects of clinician-directed and patient-directed nudges on reducing low-value care for patients with low back pain in the emergency department. Chapter Seven reports the trial's findings.

1.7 Aims and objectives of this thesis

The aim of this thesis was to evaluate available evidence for the use of behavioural economics and nudge interventions for reducing low-value care. The specific objectives of this thesis were to:

- To determine whether text-message based nudge interventions (a prize-draw incentive and pro-social framing) could increase response rates to a patient reported outcome survey in the emergency department (Chapter Two).
- To critically evaluate theory and evidence to identify behavioural economic techniques that physiotherapists can implement in daily practice to improve patient adherence to home exercise programs (Chapter Three).
- To synthesise and critically evaluate evidence on clinician-directed default nudges and their impact on reducing overuse of tests and treatments, using rigorous synthesis methods (Chapter Four).
- To determine if the number of care alternatives in suggested alternative nudges on primary care physician decisions to remain with a low-value care option or replace it with a preferred alternative (Chapter Five).
- To determine the effectiveness of patient-directed and clinician-directed nudges on reducing low-value care for patients with low back pain in the emergency department (Chapter Six and Seven).

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CHAPTER TWO: Text-Message Incentives Increased Patient-Reported Outcomes Survey Response in Emergency Care: SWAT Findings

Chapter Two presents the study within a study examining whether text-message nudge interventions (a prize-draw incentive and pro-social framing) could increase response rates to a patient reported outcome survey in the emergency department.

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ORIGINAL RESEARCH

Text message incentives increased patient-reported outcomes survey response in emergency care: SWAT findings

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Abstract

Objectives: To determine if text message−based behavioral interventions could increase response rates to a patient-reported outcomes survey in the emergency department (ED).

Study Design and Setting: We conducted a study within a trial (SWAT), within the NUDG-ED trial. The NUDG-ED trial aimed to reduce low-value care for patients with back pain presenting to eight EDs in Sydney, Australia. This SWAT was a 3-arm randomized controlled trial (RCT) nested within the NUDG-ED trial. After discharge from the ED, patients were randomized to receive one of the three text message invitations to complete a follow-up patient-reported outcome survey: a standard control message, or one of two behaviorally informed messages including either a prize draw incentive or prosocial framing. Our primary outcome measure was the response rate in each study group. We performed a linear mixed-effects model controlling for hospital heterogeneity and patient characteristics to estimate the mean difference (MD) in proportions with 95% CI, to determine the effectiveness of the behavioral interventions.

Results: A total of 1494 patients were randomized between May 15, 2024 and January 29, 2025. Of these, 52% were women, the median age was 46 years (IQR 35, 62), 43% were from disadvantaged areas and 51% were triaged with a clinically urgent condition. Baseline characteristics were balanced across all groups. Our primary analysis found that compared to the control, the prize draw incentive increased response rates (n = 997 patients, MD = 6.9%, 95% CI: 1.8% to 11.9%, P = .007). Our adjusted mixed-effects model also found a significant increase in response rates (n = 979 patients, MD = 6.4%, 95% CI 1.3% to 11.4%, P = .013). Compared to the control, the prosocial framing message may have slightly increased response rates, but the results were not statistically significant (n = 996 patients, 17.2% vs 21.1%, MD = 3.9%, 95% CI: −1.1% to 8.9%).

Conclusion: In this randomized trial, a prize draw incentive modestly improved response rates to a patient-reported outcomes survey in routine emergency care settings. Prosocial framing may have slightly increased response rates, but the effect was uncertain. Both behavioral approaches warrant further testing in routine care settings.

Keywords: Randomized controlled trial; Pragmatic trial; Emergency department; Patient-reported outcomes; Behavioral interventions; Nudge interventions

1. Introduction

Pragmatic trials embedded in routine clinical practice maintain the rigor of randomized controlled trials (RCTs) while providing more relevant, generalizable evidence [1,2]. Pragmatic trials offer real-world insights that are more likely to inform clinical practice and be implemented effectively [3]. However, there are considerable challenges in conducting pragmatic trials. For instance, patient-reported outcomes are crucial in evaluating the effects of clinical interventions, yet can be difficult to collect in

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Plain Language Summary

Patient-reported outcomes, such as surveys about how people feel and recover after care, are important for understanding what matters most to patients. However, response rates to these surveys are often very low, especially in real clinical settings. This makes it difficult to draw strong conclusions about whether treatments are helping patients. So, researchers and health services need to find ways to improve response rates. This study looked at whether simple text message strategies could encourage more patients to complete follow-up surveys after visiting the ED for low back pain. We conducted a RCT involving 1494 patients in Sydney. After being discharged from the ED, patients were randomly assigned to receive one of the three text message invitations to complete a survey: a standard message, a message offering entry into a prize draw, or a message using prosocial wording (emphasizing how their response could help others). We found that patients who received the prize draw message were more likely to complete the survey. About 24% responded to this message, compared to 17% who received the standard message, an increase of around 7%. We are uncertain whether the prosocial message was effective. These findings suggest that adding a prize draw incentive to a text message-based study invitation can modestly increase survey participation in routine health-care settings. Improving response rates helps ensure that patient perspectives are more accurately represented in research and health-care improvement efforts. Further studies are needed to confirm these results and explore other effective ways to increase participation.

routine care [4,5]. Response rates to patient-reported outcome surveys in trials conducted in routine health services could be as low as 2.6% [6].

Low response rates pose significant challenges in clinical trials, particularly when follow-up survey respondents differ systematically from nonrespondents. If those who respond are not representative of the original trial population, the advantages of randomization can be severely compromised [7]. This introduces risks of selection and nonresponse bias, which in turn can undermine the validity of conclusions drawn about treatment effectiveness, safety, and quality of care more broadly [8,9]. In the United States, participants who respond to patient-reported outcomes surveys are typically older, more likely to be White, and from higher socioeconomic backgrounds compared to nonresponders [10−12]. In contrast, an analysis of surgical patients in England (n = 131,447) found that late and nonresponders were more likely to have severe health conditions, poorer recovery, and lower quality of life [8]. Such discrepancies between responders and nonresponders can result in substantial bias within clinical trials [7−9].

The emergency department (ED) presents unique challenges for collecting patient-reported outcomes in pragmatic trials due to high patient volume, urgent care needs, and the severity of symptoms. Back pain is a common presenting health problem in this setting. Patients with back pain who present to the ED typically report higher pain and disability levels than those presenting to primary care [13]. In addition, individuals with chronic pain in the ED are more likely to be from vulnerable populations and may experience greater distress at the time of presentation [14]. Despite the potential benefit of including patient-reported outcomes, research conducted in emergency care settings rarely includes patient-reported outcomes with high response rates [15,16]. Therefore, effective strategies for optimizing patient-reported outcome response rates in ED trials are essential.

Various strategies have been proposed to improve patient-reported outcome survey response rates. A systematic review of 117 studies, including trials, methodology papers, and surveys of practice, found that training trial staff, appointing coordinators, and ensuring adequate resources were among the most effective recommendations for improving patient-reported outcome data quality [17]. However, these strategies are resource-intensive and may not be feasible for trials embedded in routine care settings.

Less resource-intensive strategies are required to improve response rates for pragmatic trials. One potential strategy to enhance response rate is offering extrinsic rewards, such as entry into a prize draw. A Cochrane meta-analysis of 16 trials (38,901 participants) found that providing an incentive, including prize draws and gift cards, improved survey response rates compared to no incentive (odds ratio [OR] 1.60; 95% CI: 1.25−2.05) [18]. However, the effect varied considerably across studies (I^2 = 93%), and effects in pragmatic trials remain unclear [18]. An alternative approach is using prosocial framing in the survey invitation. Prosocial framing emphasizes how a participant's behavior can benefit others. This strategy uses the intrinsic motivation theory that people may be more willing to engage in tasks they believe will help others [19,20]. The same Cochrane review found that prosocial framing increased survey response rates (OR 1.38; 95% CI: 1.07−1.78; I^2 = 41%) in some contexts, although evidence in health care has been mixed. [21−24]. Neither of these behavioral interventions has

What is new?

Key findings

- Response rates to patient-reported outcome surveys are typically low.
- Text message based behavioral strategies increased response rates in emergency care patients.

What this adds to what is known?

- This study shows that behavioral strategies are feasible and effective in clinical settings.

What is the implication and what should change now?

- Such strategies could enhance data quality and facilitate patient-centred evaluations of care.

been evaluated in trials embedded in routine emergency care.

2. Aims

This study investigated whether behavioral strategies could improve response rates for patient-reported outcomes following discharge from the ED. Specifically, we tested the effectiveness of two text message–based behavioral strategies—a prize draw incentive and prosocial framing—compared to a standard text message invitation. The primary comparison of interest was the prize draw incentive compared to the control on response rates.

3. Methods

3.1. Trial design

We conducted a study within a trial (SWAT) by nesting a RCT within the NUDG-ED trial [25]. The aim of NUDG-ED is to reduce unnecessary imaging and opioids for patients with uncomplicated low back pain presenting to the ED. The trial is described in detail elsewhere and ran between 15 May 15, 2024 and January 29, 2025 [25].

This SWAT was a 3-arm trial that examined the effectiveness of text message invitations with either a prize draw incentive or prosocial framing, compared with a standard invitation on response rates to a patient-reported outcome survey. We registered our protocol online [26] and received ethical approval from the Southwestern Sydney Local Health District Human Research Ethics Committee (2023/ETH00472). CONSORT and SWAT reporting guidelines for randomized studies within a trial have been followed (Supplement 1) [27].

3.2. Setting and participants

NUDG-ED included eight public hospital EDs in culturally diverse, metropolitan areas of Sydney, Australia. To be enrolled in NUDG-ED, patients had to present to the ED with back pain, have a diagnostic code for a back pain-related musculoskeletal condition, and be $\geq$18 years old. To be included in the SWAT, patients also needed to have a mobile phone number recorded in their health record, not require a translator during their ED visit, and have been discharged from ED within the past week. We screened and randomized eligible patients each week during the trial.

We collected baseline characteristics including sex, age, language spoken at home, and postcode from the health service as part of the NUDG-ED trial. We estimated socioeconomic status by matching patients' postcodes with the relevant Index of Relative Socioeconomic Advantage and Disadvantage (IRSAD) deciles, with first to fifth deciles indicating relatively disadvantaged suburbs [28]. We also collected relevant health service data including triage category, whether patients arrived by ambulance, whether they were admitted, and length of stay. Triage categories 1-3 are considered more urgent according to the Australasian Triage Scale [29].

3.3. Randomization and blinding

We used a computer-generated random number list to randomize eligible patients into one of the three groups (control, a prize draw incentive or prosocial framing). Randomization was implemented by a blinded database manager from the Australian National Health and Medicine Research Council Clinical Trials Center. To reduce the potential impact of hospital-level factors on our outcome of interest, we stratified randomization by hospital site. Eligible patients were consecutively enrolled over a 24-week period until each of our eight sites reached their quota of 192 per site. Participants and researchers were blinded to group allocation to ensure internal validity was not compromised.

3.4. Interventions

All text messages were personalized with the patient's name, hospital name, and addressed from the ED director of the hospital they presented to (Box 1). All text messages included the link to the patient-reported outcome survey and information on how to stop receiving further messages. If the trial team received no response or no request to stop receiving text messages within 24 hours following the index message, a second identical message was sent the following day, and a third message the day after that.

3.5. Outcomes

Our outcome measure was the response rate to the patient-reported outcomes survey invitation. We considered

Box 1 Text message invitations sent to the study groups

Intervention components highlighted.

Control

Dear Jane, We hope you are going well after your recent visit to our emergency department. We are interested in what you thought of our care. This voluntary survey will only take 5 minutes to complete. To begin the survey, visit [Hyperlink]. To opt out reply STOP or ignore this invitation. Your responses will contribute to a study being conducted by our department and [Lead Investigator name] from The University of Sydney. Kind regards, [ED Director name], Director, [Hospital name] ED If the link above does not work, try copying the link into your web browser. This link is unique to you and should not be forwarded to others.

Prize draw incentive

Dear Jane, We hope you are going well after your recent visit to our emergency department. We are interested in what you thought of our care. This voluntary survey will only take 5 minutes to complete. Complete the survey for your chance to win one of 10 Myer Gift Vouchers valued at $100. To begin the survey, visit [Hyperlink]. To opt out reply STOP or ignore this invitation. Your responses will contribute to a study being conducted by our department and [Lead Investigator name] from The University of Sydney. Kind regards, [ED Director name], Director, [Hospital name] ED If the link above does not work, try copying the link into your web browser. This link is unique to you and should not be forwarded to others.

Prosocial framing

Dear Jane, We hope you are going well after your recent visit to our emergency department. We are interested in what you thought of our care. This voluntary survey will only take 5 minutes to complete. Your feedback will help us improve care for people with back pain in the ED. To begin the survey, visit [Hyperlink]. To opt out reply STOP or ignore this invitation. Your responses will contribute to a study being conducted by our department and [Lead Investigator name] from The University of Sydney. Kind regards, [ED Director name], Director, [Hospital name] ED If the link above does not work, try copying the link into your web browser. This link is unique to you and should not be forwarded to others.

a participant as having responded if they initiated the survey.

3.6. Statistical analysis

We calculated the proportion of participants responding to the patient-reported outcomes survey text message invitation in each intervention group. Our primary comparison of interest was the effect of the prize draw incentive compared with the control text message invitation. For our primary analysis, we performed a linear mixed-effects model, including text message group as a fixed effect and hospital site as a random effect. Adjusted analyses controlled for patient characteristics (gender, age, socioeconomic status, and language spoken at home). We estimated the mean difference (MD) in proportions with 95% CI to determine the effect of the prize draw incentive on response rates in comparison to the control. For our secondary analysis, we conducted pairwise comparisons to explore the effectiveness of the prosocial framing compared to the control, and the prize draw incentive compared to the prosocial framing. Subgroup analyses were performed to explore whether patient characteristics (socioeconomic status and language spoken at home) influenced the effectiveness of the prize draw incentive or prosocial framing intervention [30,31]. We described the characteristics of responders and nonresponders and the proportion of patients requesting to no longer receive text messages in each group.

3.7. Sample size calculation

Sample size was calculated based on the primary comparison of response rates between the control and prize draw incentive. A sample size of 512 per arm (a total of 1024 for primary analysis) was required to achieve 80% power at 5% significance level to detect 9% difference between the prize draw and control.

4. Results

A total of 1785 encounters for patients with musculoskeletal back pain were screened for eligibility between May 15, 2024 and January 29, 2025. A total of 291 patients did not meet our eligibility criteria and were excluded. A total of 1494 patients were enrolled and randomized into three groups: control, prize draw incentive, or prosocial framing. Overall, 997 patients were included in the primary analysis comparing the effect of the prize draw incentive against the control (Fig). For our mixed-effects models, 18 patients were excluded from the adjusted analysis due to missing postcodes required to identify IRSAD deciles.

Of the 1494 patients enrolled in this nested trial, 52% were women, the median age was 46 years (IQR 35, 62) and most spoke English at home (87%). Just over half (57%) of patients lived in areas that had higher

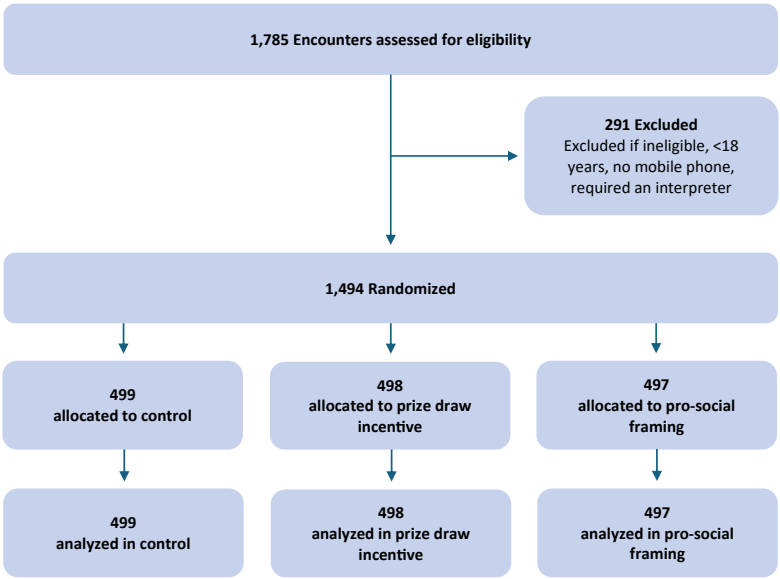

Figure 1. Participant flowchart and randomization in nested trial.

Table 1. Baseline characteristics of study participants

Baseline characteristic	Control $N = 499$[a]	Prize draw incentive $N = 498$[a]	Prosocial framing $N = 497$[a]
Sex			
Female	259 (52%)	256 (51%)	262 (53%)
Male	240 (48%)	242 (49%)	235 (47%)
Age	46 (34, 63)	46 (36, 62)	45 (34, 63)
Language spoken at home			
English	427 (86%)	437 (88%)	439 (88%)
Non-English language	72 (14%)	61 (12%)	58 (12%)
IRSAD			
Advantaged postcode	291 (58%)	284 (57%)	276 (56%)
Disadvantaged postcode	202 (40%)	210 (42%)	213 (43%)
Missing or interstate postcode	6 (1.2%)	4 (0.8%)	8 (1.6%)
Triage category (1-3 is urgent)			
2	18 (3.6%)	28 (5.6%)	31 (6.3%)
3	241 (48%)	226 (45%)	216 (44%)
4	229 (46%)	233 (47%)	242 (49%)
5	11 (2.2%)	11 (2.2%)	8 (1.6%)
Arrived by ambulance	191 (38%)	184 (37%)	189 (38%)
Median hours in ED	6 (4, 11)	6 (4, 11)	7 (4, 12)
Admitted to hospital	130 (26%)	119 (24%)	136 (27%)
Left without treatment	38 (7.6%)	28 (5.6%)	27 (5.4%)
Represented within 30 days	38 (7.6%)	26 (5.2%)	37 (7.4%)

ED, emergency department; IRSAD, Index of Relative Socioeconomic Advantage and Disadvantage.
[a] n (%); median (IQR).

Table 2. Unadjusted and adjusted effects behavioral interventions on patient-reported outcome survey response rates

Variables	Control $N = 499$[a]	Prize draw incentive $N = 498$[a]	Prosocial framing $N = 497$[a]	Unadjusted effect[b] MD (95% CI)	Adjusted effect[c] MD (95% CI)
Primary outcome: control vs prize draw incentive	86 (17.2%)	120 (24.1%)	-	6.9% (1.8% to 11.9%), $P = .007$	6.4% (1.3% to 11.4%), $P = .013$
Secondary comparisons: control vs prosocial framing	86 (17.2%)	-	105 (21.1%)	3.9% (−1.1% to 8.9%)	3.2% (−1.8% to 8.3%)
Prize draw incentive vs prosocial framing	-	120 (24.1%)	105 (21.1%)	−3.0% (−8.0% to 2.1)	−3.1% (−8.2% to 1.9%)

MD, mean difference.
[a] N (%) response.
[b] Linear mixed model with message as fixed effect and hospital as random effects.
[c] Additional adjusted variables: gender, age, socioeconomic status and language spoken at home.

socioeconomic status and were more advantaged by IRSAD. On arriving to the ED, no patients were triaged as needing immediate treatment (triage category 1). About half of the included patients were triaged to category 2 and 3, as needing urgent treatment or having a serious condition (51.2%), with the remaining assessed as moderate or nonurgent (49%). Just over a third of patients arrived by ambulance (38%) and around a quarter were admitted to hospital (26%). The median length of stay in the ED was 6 hours (IQR 4 hours, 11 hours). Baseline characteristics were balanced across all the three groups (Table 1).

Compared to the control, a prize draw incentive increased response rates to a text message invitation from the hospital to complete patient-reported outcomes survey (control: 17.2% vs prize draw incentive: 24.1%). Our models estimated significantly higher response rates in both unadjusted ($n = 979$ patients, MD = 6.9%, 95% CI: 1.8%−11.9%, $P = .007$) and adjusted (MD = 6.4%, 95% CI 1.3%−11.4%, $P = .013$) models (Table 2).

Our secondary analysis found that compared to the control, prosocial framing may have slightly increased response rates, but the results were not statistically significant (control: 17.2% vs prosocial framing: 21.1%, MD = 3.9%, 95% CI: −1.1% to 8.9%, $P = .129$) (Table 2). There was no difference in requests to no longer receive text messages between groups.

Exploratory subgroup analyses found no interaction between socioeconomic status and language spoken at home, and any intervention effects ($P = .195$). The characteristics between non-responders and responders were roughly the same across the three intervention groups (Table 3). Compared to responders in the control group, responders in the intervention groups were slightly more likely to be female, younger, and from more socioeconomically disadvantaged areas.

Table 3. Characteristics between nonresponders and responders stratified by intervention group

	Control		Prize draw incentive		Prosocial framing	
Baseline characteristic	Nonresponders $N = 413$[a]	Responders $N = 86$[a]	Nonresponders $N = 378$[a]	Responders $N = 120$[a]	Nonresponders $N = 392$[a]	Responders $N = 105$[a]
Sex						
Female	219 (53%)	40 (47%)	192 (51%)	64 (53%)	200 (51%)	62 (59%)
Male	194 (47%)	46 (53%)	186 (49%)	56 (47%)	192 (49%)	43 (41%)
Age	45 (33, 62)	53 (37, 65)	47 (35, 63)	46 (37, 59)	44 (33, 63)	50 (38, 62)
Language spoken at home						
English	347 (84%)	80 (93%)	327 (87%)	110 (92%)	341 (87%)	98 (93%)
Non-English language	66 (16%)	6 (7.0%)	51 (13%)	10 (8.3%)	51 (13%)	7 (6.7%)
IRSAD						
Advantaged postcode	240 (58%)	51 (59%)	221 (58%)	63 (53%)	229 (58%)	47 (45%)
Disadvantaged postcode	167 (40%)	35 (41%)	154 (41%)	56 (47%)	157 (40%)	56 (53%)
Missing or interstate postcode	6 (1.5%)	0 (0%)	3 (0.8%)	1 (0.8%)	6 (1.5%)	2 (1.9%)

IRSAD, Index of Relative Socioeconomic Advantage and Disadvantage.
[a] *n* (%); Median (IQR).

5. Discussion

5.1. Main findings

Our results indicate that offering a prize draw in a text message invitation can increase response rates for a patient reported outcome survey in a routine ED setting. Prosocial framing may have had a positive effect on response rates; however, CIs were wide and included the null.

Although these behavioral interventions are not a panacea, including a prize draw incentive or a prosocial framing interventions in text message−based communications from health services, may increase response rates to routinely collected patient-reported outcome surveys.

5.2. Comparison to existing evidence

There is mixed evidence on strategies for improving response rates to follow-up surveys collecting patient-reported outcomes in clinical settings. Much of the existing literature focused on reminders [32,33], gifts (eg, pens) [34,35], and personalization [36] and generally had little effect. However, the baseline response rates without intervention in these studies were high, ranging from 84% [36] to 95.8% [35].

Unlike the standard randomized trials with detailed consent procedures, baseline response rates are considerably lower in routine settings. A recent annual state government survey distributed to a random sample of patients discharged from EDs in the same setting as our larger trial (Western Sydney and South Western Sydney Local Health Districts) achieved response rates of 15.4% and 17.7%, respectively [37]. A trial during COVID-19 had a response rate of 2.6% [6]. In these contexts, it is possible that even a modest absolute improvement of 7% in survey response could influence trial conclusions. In their investigation capturing the 'Fragility Index' of 399 RCTs, Walsh et al [38] found that trial fragility depends heavily on sample size and the frequency of the outcome of interest. Modest increases in response rates are therefore only likely to influence trial conclusions in small trials with low-frequency binary outcomes.

5.3. Strengths

This study has several strengths. First, this trial was nested in a large pragmatic trial within eight hospital EDs, a setting well known for being challenging to collect patient-reported outcomes [15]. Our trial demonstrates the feasibility of testing behavioral interventions to increase collection of patient-reported outcomes in routine care using robust methods. Second, stratified randomization was used to minimize hospital-level effects and participants and researchers were blinded to reduce selection and performance bias. Lastly, the behavioral interventions examined in this trial are relatively low cost and easily implementable in real clinical settings.

5.4. Limitations

This study is not without limitations. It was conducted in patients who presented to the ED with back pain and may not be generalizable to other patient populations. However, some evidence suggests that patients with more severe conditions may be less likely to respond to patient-reported outcomes surveys [8,39]. As such, these interventions may have different effects in different care settings and patient populations. Furthermore, some participants may have suspected the text message invitations were scams. Awareness of scams has increased in Australia following the 2023 establishment of the National Anti-Scam Center [40]. There are also routine ED surveys sent out to patients in our health system, meaning participants could have received more than one invitation [37]. Both factors may have reduced patients' willingness to respond using the invitation link. Finally, the study was underpowered to detect differences in secondary and subgroup analyses.

5.5. Implications for policy, practice, and research

The ethics of using incentives for trial participation have been debated. One concern is that incentives might diminish participants' perceptions of risk, potentially compromising informed consent [41,42]. However, two RCTs involving 646 participants found no evidence that incentives led individuals to accept greater risks than they would have otherwise [42]. Another concern is whether offering incentives represents an appropriate use of research funds. Ethical guidelines support fair compensation for participants' time [43]. Furthermore, failing to optimize response rates could constitute insufficient effort to maximize scientific validity, resulting in research waste and imposing undue burden on participants [44].

Based on our secondary analysis, applying either intervention message to the full sample may have produced a slightly different composition of respondents (Table 3). In our data, women appeared to be more responsive to the prosocial framing message (47% of responders were women in the control vs 53% in the prosocial framing group). People from more disadvantaged areas also appeared slightly more responsive to the prosocial framing message (41% of responders were from disadvantaged areas in the control vs 53% in the prosocial framing group). Although exploratory, our secondary data suggest these interventions could have improved the overall representativeness of the larger trial. We found no evidence of either intervention increasing inequity of responders.

There are several opportunities for future research. Additional behavioral strategies could be tested, either alone or in combination. For instance, offering a choice of prizes may increase the perceived value of the incentive, allowing patients to opt for incentives that align with their existing preferences. [45] Health-care services could implement pseudorandomization to test framing effects and

improve response rates for surveys already being distributed [46].

Subgroup analyses across settings and interventions could identify the factors that most influence response rates, particularly in underrepresented populations [47]. As health care shifts toward a patient-centered, value-based model, improving response rates for patient-reported outcomes will become increasingly important not only for trialists but also for health services conducting routine audits of care quality [48]. However, it is important to identify opportunities to harmonize patient-reported outcome processes between researchers, health services, and health agencies to avoid duplication. Partnering to streamline these initiatives could reduce burden on patients and potentially improve response rates.

6. Conclusion

By using a SWAT design, we demonstrated that text message−based prize draw incentives can increase response rates to patient-reported outcome surveys in routine clinical settings. The effect of prosocial framing was uncertain. Both behavioral strategies warrant further testing in routine care settings.

Ethics statement

This study has ethical approval from Southwestern Sydney Local Health District Human Research Ethics Committee (2023/ETH00472). Consent for publication is not applicable as all data used were anonymous and reported in aggregate form.

Consumer involvement

Two NUDG-ED consumer advisors were appointed and provided feedback in the inception of the trials, including the study design, patient facing materials, and patient-reported outcome measures.

Costs associated with the SWAT

An economic analysis is planned for the NUDG-ED trial which tabulate the costs of this nested study.

CRediT authorship contribution statement

Gemma Altinger: Writing − original draft, Visualization, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. **Sweekriti Sharma:** Writing − review & editing, Project administration, Methodology, Investigation, Conceptualization. **Qiang Li:** Methodology. **Anthony Devaux:** Formal analysis. **Samantha Darby:** Software, Project administration, Methodology. **Aidan van Wyk:** Project administration, Methodology, Investigation. **Caitlin M.P. Jones:** Writing − review & editing, Supervision. **Chris G. Maher:** Writing − review & editing, Supervision, Methodology. **Adrian C. Traeger:** Writing − review & editing, Visualization, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization.

Declaration of competing interest

There are no competing interests for any author.

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Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jclinepi.2025.112116.

Data availability

The data that support the findings of this study are available from ACT, on request and ethics approval.

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CHAPTER THREE: Using behavioural economics to improve adherence to home exercise programs

Chapter Three presents an invited editorial that evaluated theory and evidence to identify behavioural economic techniques that physiotherapists can implement in daily practice to improve patient adherence to home exercise programs.

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Editorial

Using behavioural economics to improve adherence to home exercise programs

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Introduction

Treatment adherence could be an important factor that influences outcomes of patients undergoing physiotherapy care.[1] Guidelines from the American College of Sports Medicine suggest that optimal regimens to improve strength, cardiorespiratory fitness, agility and flexibility would typically not be achieved through supervised clinic sessions alone.[2] Most patients will require a home exercise program. Physical activity guidelines suggest that strength exercises should be performed at least 2 days per week,[3] and falls prevention guidelines suggest that balance and functional exercises should be performed at least 3 times per week.[4] Despite potential benefits, home exercise programs can have adherence levels as low as 30%.[5] In response to poor adherence rates, the World Health Organization has identified improving patient adherence to self-management treatment for chronic conditions as a research priority.[6] They also emphasise the need for a multidisciplinary approach, bringing together healthcare professionals, researchers and policymakers to test behaviourally sound interventions.[6]

There are many documented factors contributing to non-adherence to home exercise programs, including patient attitudes, self-efficacy and motivation.[7] Even when there is capability, capacity and motivation, there is a gap between a patient's good intentions and actually doing their home exercises.[8] A meta-analysis of 10 studies with 3,899 participants estimated that only 54% of people who intended to perform physical exercises actually followed through.[8]

Research in the field of behavioural economics (which brings together insights and approaches from psychology, economics and neuroscience in the study of decision-making and human behaviour) can help to understand why many people who intend to exercise ultimately do not. Research on exercise adherence shows that people are forgetful and struggle to find time in their daily routine and to change long-held habits.[7] A behavioural economist might suggest that people struggle because the benefits are usually not felt immediately, but the costs to perform the habits are (time, effort, money and pain).[9]

> *Consider the case of Joe, a 65-year-old man with knee osteoarthritis, significant stiffness and mild to moderate pain. You have been working with him once a week in the clinic to increase his strength and mobility. Joe admits that he does not often do his home exercise program. He says he sometimes does it the day after or the day before his regular appointment, but generally forgets. Sometimes he remembers at the end of the day or if he has pain, but by then he is either too tired or sore to do the exercises.*

Joe's physiotherapist might typically approach this non-adherence by building a trusting relationship, tailoring his treatment, and providing support and encouragement. However, physiotherapists could also borrow the following strategies from behavioural economics to help their patients turn intention into action (see Box 1).

Make it matter

Health decisions can be influenced by how communication is framed.[10] When discussing the importance of adherence, focusing on the benefits of doing the exercises (gain-framed approach) could be more effective than focusing on the harms of not doing them (loss-framed approach).[10] According to a large meta-analysis involving 94 studies of preventive behaviours, gain-framed messages were more effective than loss-framed messages at encouraging a number of prevention behaviours (r = 0.083, 95% CI 0.03 to 0.13), including exercise (r = 0.160, 95% CI 0.05 to 0.26).[10]

One approach is to help the patient identify tangible ways that adherence can improve their life. For example, 'improved mobility' can be abstract and may not mean much to many patients, but identifying the personal and meaningful benefits of treatment can be intrinsically motivating.[11] These newly framed goals are likely to generate cues in everyday life that remind and motivate adherence to the patient's goals.

> *Joe has previously acknowledged that he should do his exercises, but his vision for his progress has lacked personal value and the full potential of the benefits has always felt out of reach. In discussions with Joe, he tells you that he would love to be able to play with his grandchildren without fear of pain flares. This is a meaningful goal for Joe, but also salient, with more relatable measures of success than 'improved mobility'. There are also likely to be cues in his environment (eg, a photo of his family) that remind him why treatment matters to him.*

Be selective, together

Take a collaborative approach to designing a home exercise program. Being too ambitious can also impede success, particularly among those who have struggled with adherence previously.[12] A cohort study looking at improving adherence to a home exercise program among patients with neck and low back pain found that those with six or more exercises had lower odds of adherence than those with three or fewer (OR 0.2, 95% CI 0.1 to 0.9, n = 184).[13] As past adherence is a predictor of future adherence, starting small and taking the time to build trust and buy-in can play a positive role in reshaping a patient's relationship with doing their exercises.

In addition, giving patients an active choice in designing their treatment plan can enhance their commitment to it. Patients are

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Box 1. Summary of behavioural economic strategies to improve adherence to at-home exercise programs.

Make it matter
Help your patient choose personal, tangible and meaningful goals.
Be selective, together
Let your patient practise and choose their favourite exercises to take home.
Plan for the future
Use planning prompts, habit stacking and temptation bundling to increase adherence.
Maintain the habit streak
Encourage patients to track their habit and maintain the daily streak.
Do not let setbacks derail progress
Use supportive approaches to get back on track.

likely to choose the exercises that they like the most, foresee the least difficulty with and most align with their preferences. This evaluation of the exercises by the patient can increase their autonomy, self-efficacy and self-determination, which are key factors in treatment adherence.[11]

Joe practises five exercises in clinic that you think are suitable for his home treatment plan. You then discuss which of these exercises he prefers and let him pick the two to three exercises for this week's home exercise plan.

Plan for the future

It is difficult to establish new habits; we tend to revert to usual routines or the status quo.[14] The following techniques can help patients foresee barriers to completion, identify solutions, leverage existing habits and create immediate rewards for completing exercises.

Planning prompts

Many patients may leave the clinic feeling confident about how easy the exercises will be, how long they will take and the likelihood that they will remember to do them.[15] This overconfidence can lead to procrastination, forgetting and non-adherence. The use of 'planning prompts' can help prepare patients to follow through with the exercises.[16] Planning prompts involve getting patients to create a concrete exercise plan. Asking them to explain the when, where and how of their prescription encourages them to consider any barriers and creates a process that they can follow. This strategy has been shown to be effective at increasing vaccination rates, screening participation, medication adherence and appointment attendance.[16] In addition, a meta-analysis of 24 studies by Belanger-Gravel et al found that adding planning prompts to an exercise prescription had a small to medium effect on increasing physical activity (SMD 0.31, 95% CI 0.11 to 0.61).[17]

Habit stacking

We all have daily habits that operate largely outside of our conscious thought: making coffee, brushing our teeth and driving to work. These behaviours are linked and cued by contextual factors: the location, time of day, preceding actions or a person.[14] Rather than starting from scratch when trying to build habits, linking or 'stacking' new habits with existing ones can be an easier and more effective strategy.[14] Some randomised controlled trials investigating the use of habit stacking have found that it can be an effective technique for increasing a range of healthy habits. For example, a recent trial involving 101 participants found that habit stacking increased participant adherence to their targeted behaviour of meditation (OR 1.14), although this estimate came with substantial uncertainty (95% CI 1.02 to 1.33).[18] Habit stacking could look like 'if then' plans, for instance: *if* I brush my teeth, *then* I do my home exercises. This approach leverages the established habitual patterns of the morning routine. To strengthen establishing it as a cue, reminders or visual cues can be placed within the established habit that is being 'stacked' onto, for example: if 'brushing teeth' is the cue, a home exercise reminder on a sticky note can be placed on the bathroom mirror.

Temptation bundling

Many patients find that doing their exercises is not fun, but they know they *should* do it. If patients experience some enjoyment as part of doing their exercises, they are more likely to adhere to their treatment program. 'Temptation bundling' can help motivate patients by pairing an activity that they *should* do with an activity that they *want* to do.[14] This could look like doing exercise while watching an episode of their favourite TV show, listening to an audiobook or calling a friend. A field experiment involving 6,792 participants found that those who were provided with a free audiobook by their gym visited the gym 18% more frequently than those in the control condition.[19]

You work with Joe to plan when, where and how he will do his exercises. Because Joe is prone to forgetting and has more energy in the morning, you discuss habit stacking as part of his morning routine. You agree to try to stack his treatment plan on after he brushes his teeth. You suggest that he puts a sticky note on his mirror to remind him, until brushing his teeth becomes the habitual cue. To make the process more rewarding, he decides to call a friend while doing his exercises, and his children on the weekend.

Maintain the habit streak

Tracking progress can help people form habits by acting as a cue, increasing visibility of progress and providing positive feedback.[20] 'Streak tracking' involves people marking or ticking off every day that they complete a desired task. Streak tracking rewards participation rather than outcomes. Nine controlled experiments by Silverman et al found that streak tracking created greater commitment to goals, including diet and exercise.[20] In addition, a randomised trial found that of 601 participants who all completed strength exercises, those who were randomised into a 'streak logged' compared with a 'streak not logged' group were more likely to engage with the exercises (66% versus 58%, OR 1.43, 95% CI 1.03 to 1.99)[a].[21]

Physiotherapists will often provide illustrated or video instructions to support patients; streak tracking is a tool that can be added to this process. Depending on patient preferences, this could include a printout of a one-page calendar, diarising adherence or using a free streak-tracker app. This can be strengthened by writing goals and planning prompts on the calendar printout, in the diary or within the streak-tracker app.

Joe has started ticking off each day he completes his exercises on a printout calendar you have provided. He has found the visual reminder of his progress motivating and does not want to break his streak.

Do not let setbacks derail progress

Broken streaks can be demotivating, with patients giving up if they forget a day, so it is important to discourage an 'all or nothing' approach. Evidence suggests that flexibility does not reduce consistency – it increases it.[22] Habits form and are best maintained in a stable context, so if people are traveling or have lots of disruptions to their daily context, encourage them to resume them once their context is more stable again.[14]

Clinicians should celebrate successes and never criticise non-adherence.[12] Taking an approach of unconditional acceptance and collaborative problem-solving could help understand and overcome

barriers. Maintaining a trusting and supportive clinician-patient relationship is important to achieving long-term behaviour change.[12]

If patients have lost momentum, take advantage of fresh start effects. Dai et al found that landmarks in time helped separate past struggles in goal concordant behaviour and reset motivation towards goals. They found that people were more likely to initiate or recommence goal-driven behaviour like exercise and gym attendance at the start of new temporal landmarks. For example, student participants were more likely to go to the gym at the beginning of the week (by 34%), month (by 15%), year (by 12%), semester (by 48%) and following holidays (by 25%) and birthdays (by 8%).[23]

Joe found it difficult to maintain his daily streak over the Christmas period, with disruptions to his regular routine. You reassure him that short-term disruptions are fine and to be expected, but the start of the new year is a perfect time to start afresh.

Conclusion

Behavioural economics has provided evidence that simple strategies can help increase adherence to treatment. Strategies that help patients to identify meaningful goals, co-design their program, plan how they will do the exercises and maintain their streak can help them to adhere to their treatment plans. These techniques have been used to improve a variety of health-related behaviours and habits. Physiotherapists can implement these techniques in their daily practice.

Footnotes: [a] 95% CI calculated by the authors from data in the original paper.

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CHAPTER Four: Effectiveness of clinician-directed default nudges on reducing overuse of tests and treatments in healthcare: a systematic review of randomised controlled trials

Chapter Four presents the first systematic review to synthesise and critically evaluate evidence on clinician-directed default nudges and their impact on reducing overuse of tests and treatments.

Citation

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Effectiveness of clinician-directed default nudges on reducing overuse of tests and treatments in healthcare: a systematic review of randomised controlled trials

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ABSTRACT

Objective To evaluate the effectiveness of clinician-directed default nudges for reducing overuse of tests and treatments.

Design A systematic review was conducted to synthesise evidence from randomised controlled trials examining the effect of clinician-directed default nudges on overuse of tests or treatments, measured as a proportion of encounters or patients. Four databases and three clinical trial registries were searched up to 13 January 2025. Two reviewers screened, extracted data, assessed risk of bias and certainty of evidence using Cochrane guidance. Because there was high clinical heterogeneity, we used the Synthesis Without Meta-analysis guidelines for our overall analysis. A secondary exploratory meta-analysis was performed on a subgroup of default nudge interventions targeting opioid prescriptions.

Results We included six trials (five cluster randomised trials and one patient randomised trial, n=767 to 21 331). Trials targeted overuse of opioids, antibiotics, high-risk medicines for older patients and imaging during palliative radiotherapy. Lowering default quantities of opioids may cause reductions in opioid overuse, but on one occasion increased overuse. It is unclear if opt-out defaults reduce antibiotic overuse in patients with sepsis eligible for de-escalation or if lowering default doses reduce overuse of high-risk medications in older patients. Reducing the default frequency of imaging probably causes large reductions in unnecessary imaging in people receiving palliative radiotherapy. A subgroup meta-analysis was only possible on one type of default for opioids. A 10-tablet default may reduce overuse of large packs of opioids (risk difference=−14.3%, 95% CI −51.4% to +22.9%, 3 trials, 18 186 encounters, very low certainty evidence).

Conclusions Clinician-directed default nudges had inconsistent effects on overuse of healthcare, with limited and mostly low certainty evidence. High-quality trials are essential to determine whether default nudges reduce overuse or improve patient outcomes.

PROSPERO registration number 42024516423

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Overuse of tests and treatments compromises the quality, safety and sustainability of healthcare systems globally.

⇒ Default nudges could reduce overuse by preselecting a recommended care option, but most evidence to date has been from observational studies.

WHAT THIS STUDY ADDS

⇒ First review to synthesise results from randomised controlled trials, using recommended methods to reduce risk of bias.

⇒ Clinician-directed default nudges had inconsistent effects on reducing overuse, with effects varying widely depending on clinical context and default settings.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ With few randomised trials, no data on patient outcomes and mostly low certainty evidence, more high-quality randomised trials of default nudge interventions are essential.

INTRODUCTION

Overuse of tests and treatments is a significant challenge for health systems worldwide.[1] A recent analysis estimated that about 40% of healthcare practices could be considered of limited benefit, inappropriate or harmful.[2] The prevalence of overuse of treatments such as antibiotics,

proton pump inhibitors and opioids remains high, with rates of overuse exceeding 98% of encounters in some cases.[3] Overuse of inappropriate testing also remains problematic. A 2022 systematic review found overuse of diagnostic imaging could be as high as 86% for uncomplicated back pain and 79% for baseline laboratory tests in some settings.[4] Twenty-five countries have attempted to reduce overuse of medical tests and treatments by engaging in the Choosing Wisely awareness campaign.[1] Despite increased awareness, these programmes have shown limited effectiveness in reducing overuse in practice.[5 6] There is growing evidence that addressing knowledge gaps alone may be insufficient to reduce overuse.[7]

Nudge interventions could reduce overuse by changing the way choices are presented to clinicians. Thaler and Sunstein define nudge interventions as any aspect of the 'choice architecture' that leads to predictable changes in people's decision-making and behaviour.[8] Importantly nudges do not forbid any option or change economic incentives.[9] A 'default nudge' is thought to influence behaviour by automating, prefilling or preselecting the preferred option, thereby simplifying the decision.[10–12] Unless an alternative is actively selected, then the default is chosen. Default nudges can signal which option is endorsed or recommended and could therefore discourage overuse of non-recommended options.[12] If a default is perceived as acceptable, individuals may prefer to remain with it rather than evaluate all alternatives, particularly when the alternatives may not yield better outcomes.[12–14]

In clinical settings, default nudges can be embedded in electronic health systems to influence clinician behaviour at the point of care.[15 16] For example, to address overuse, a default nudge might lower the preset number of opioid tablets from 30 to 12 for standard prescriptions.[17] However, many clinician-directed nudges within the electronic health system take the form of interruptive alerts, contributing to up to 70 alerts a clinician may be exposed to each day.[18] A retrospective cohort study of 112 primary care clinicians found that their likelihood of accepting an alert reduced by 30% for each additional alert within an encounter.[19] Unlike interruptive alerts, default nudges could be seamlessly implemented within the existing order forms, minimising disruption or alert fatigue.

Clinician-facing default nudges could reduce overuse without compromising clinicians' ability to tailor care to patient needs and preferences. Previous systematic reviews have explored the effect of different nudges on a broad range of healthcare and quality improvement behaviours.[11 20–24] Four of these identified 'default nudges' as particularly promising for shifting clinician decision-making.[11 20 21 24] However, these reviews evaluated default nudges alongside many other types of nudges and relied primarily on observational studies, making conclusions about the causal effect of the default nudges challenging. Furthermore, no review to date has evaluated the effect of default nudges using a standardised measure of overuse. As such, it is uncertain to what extent default nudges influence overuse across different clinical contexts. There have since been several cluster randomised trials published that could change the certainty of evidence on the effectiveness of default nudges to address overuse.

The aim of this systematic review was to determine the effectiveness of clinician-directed default nudges on reducing the overuse of healthcare. Specifically, our objective was to synthesise default nudge effects from randomised trials conducted across the full range of clinical contexts without restriction on the type of overuse targeted.

METHODS

This systematic review was preregistered with PROSPERO[25] and was reported in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses 2020 (online supplemental table 1) and Synthesis Without Meta-analysis (SWiM) guidelines.[26 27] SWiM guidelines are recommended when a systematic review examines the quantitative effect of an intervention, but it may be inappropriate to conduct a meta-analysis for all or some of the outcomes.[26]

Eligibility criteria

Studies meeting the following criteria were eligible: (1) randomised controlled trials; (2) conducted in real clinical settings, across any specialty; (3) targeted overuse of tests or treatments and outcomes needed to include measures of healthcare provision; (4) reported data that permitted estimation of between-group differences; (5) comparison was usual care or a 'null' default where no default was set; (6) grey literature if full results were available; (7) met our definition of a default nudge.

We defined a default nudge as an intervention where a preferred care option is preselected, and unless clinicians take action to choose otherwise, will be delivered.[10] We considered the key examples of clinician-directed default nudges to include interventions where the quantity of tablets or dose of a medicine is preselected; where the frequency of tests or treatments is preselected; or where patients are automatically enrolled onto a particular management plan. Interventions that restricted or mandated options were not considered default nudges.[10] Default nudges were eligible if they were either implemented alone (not part of a multicomponent intervention) or if methods were used to isolate the effect of default nudge. In trials that were examining the effect of a default on clinical behaviour more broadly, only the intervention arms that were aiming to reduce overuse were eligible.[28]

Outcomes

Our primary outcome was the proportion of patient encounters receiving the targeted overused test or treatment. Overuse thresholds were defined by trial authors within the context of their clinical care setting. To allow us to estimate effects on overuse across studies, we prioritised measures of overuse that were reported as a dichotomous outcome.

As a secondary outcome, we reported other potential indicators of overuse when available, such as total number of tablets and morphine milligram equivalents (MME). To investigate potential adverse effects, we extracted information related to underuse of effective care, undesirable changes to health, healthcare or health behaviours.

Search strategy

We searched Medline, CINAHL, Embase, without language or date restrictions. Additionally, we searched ClinicalTrials.gov, Australian New Zealand Clinical Trials Registry and the World Health International Clinical Trials Registry. Backward and forward citation searches were also conducted. The search strategy was developed by a behavioural economist in collaboration with a librarian and clinician authors to ensure comprehensiveness (box 1). Online supplemental table 2 presents our complete search strategy.

We attempted to contact corresponding authors when trial results were unavailable. Each author was contacted up to two times. In total, five authors were approached. Of these, three did not respond, one indicated that recruitment was ongoing, and one provided a final report submitted to funders, (Poeran J, unpublished data, 2024) which was included in our synthesis.

Study selection and data extraction

Records were uploaded to Covidence, a systematic review management platform endorsed by Cochrane.[29] Covidence identified duplicate records and flagged potentially ineligible studies if they were labelled as laboratory-based studies or systematic reviews. A reviewer (GA) manually checked these flagged records before exclusion. Two reviewers independently screened titles and abstracts to assess eligibility. Full texts of potentially eligible records were reviewed in duplicate. Two reviewers independently extracted data. Any disagreements were resolved by discussion or with a third independent reviewer.

Box 1 Search strategy summary

Our search strategy followed our PICO (Population, Intervention, Comparison, Outcome) question and had three components:

1) Intervention – terms for default nudge strategies
AND
2) Outcome – terms for the outcome of overuse
AND
3) Study design – terms for randomised controlled trials

To capture trials that did not explicitly label the intervention as a default nudge but meet our operational definition, the intervention search terms included both standard nudge terminology and related descriptors such as "automate", "preselect", and "prefill".

Data synthesis and analysis

Our primary approach to synthesis was to use SWiM guidelines for quantitative SWiM.[26] In line with these guidelines, we described the range of trial characteristics and the types of default nudges used.[26] To present effect sizes, we used unadjusted absolute risk difference as the standardised effect measure. To standardise effect sizes, we calculated the raw unadjusted proportion of encounters where the test or treatment considered overuse was provided to patients in the intervention and control groups. Using these proportions, we calculated the absolute risk difference and 95% CIs for the effect of the default nudge on overuse in the intervention group compared with the control group. This calculation did not account for intracluster correlation because this information was not available in all study reports.

We planned to conduct meta-analyses if there were sufficient trials in similar clinical care settings, targeting a similar overuse problem in similar patient populations. However, there were few trials and clinical heterogeneity was significant. As such, only one subgroup meta-analysis was conducted as a secondary analysis.[30] We conducted a random-effects meta-analysis of three comparisons using risk difference as the dichotomous outcome measure. The analysis employed the restricted maximum likelihood estimator to model between-study variance (τ^2), and Confidence Intervals (CIs) were adjusted using the Hartung-Knapp-Sidik-Jonkman method to account for the small number of included studies.[31] Heterogeneity was quantified using the I^2 statistic, with corresponding 95% CI.[32] As the meta-analysis was a secondary outcome, limited to three trials and assessed as very low certainty evidence, we did not conduct any sensitivity analyses.

Risk of bias and certainty of evidence assessment

Two reviewers independently assessed the risk of bias of included studies using the Cochrane Risk Of Bias Tool 1.[33] An additional 'Analysis' risk of bias domain relevant to analysis of cluster trials was also assessed.[34 35] For example, cluster trials were marked down in the Analysis domain if they did not report baseline data or did not account for clustering in their analysis.[34 36] Assessments were discussed and validated by a third reviewer.

Two independent reviewers assessed the certainty of evidence using the Cochrane Grading of

Recommendations, Assessment, Development and Evaluations (GRADE) system.[37] Because clinical heterogeneity was high, we assessed the certainty of evidence for each comparison. We downgraded for 'Imprecision' if the comparison had a sample size that was too small to detect a meaningful difference or if CIs included both a meaningful benefit and a meaningful harm or null effect. We downgraded for 'Inconsistency' if there was wide variation in patient populations, effect estimates and statistical heterogeneity. We downgraded for 'Indirectness' if the comparison provided evidence that was more restrictive than our review question, for example, if the evidence addressed overuse of antibiotics in a single setting for a limited group of patients but did not cover overuse of antibiotics more broadly. Publication bias was not assessed due to too few trials.[38] Assessments were discussed with a third reviewer.

RESULTS

We searched from inception to 13 January 2025 and identified 21 087 records from our database search and 114 records from our clinical registry search. 10 060 records were marked as duplicates or ineligible by Covidence and checked by a reviewer. Two duplicates were manually removed. 11 139 title and abstracts were screened, and 68 full text records were assessed for eligibility (figure 1). 57 records were excluded, with the most common reason for exclusion was the intervention not meeting our definition of a default nudge (online supplemental table 3). In total, six randomised controlled trials,[28] (Poeran J, unpublished data, 2024)[39–42] reported in 11 records,[28 39–41 43–47] were included (online supplemental table 4).

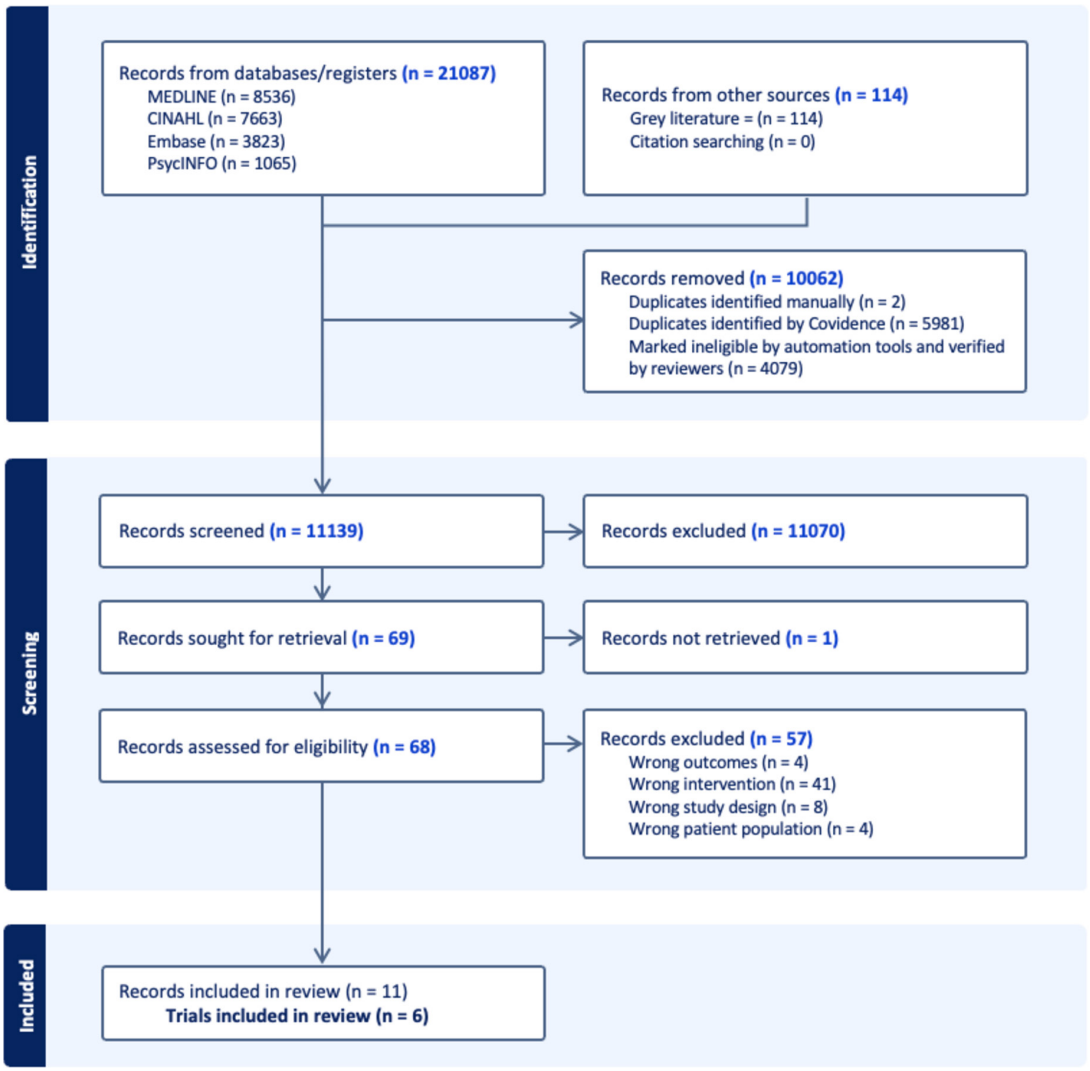

Figure 1 PRISMA flowchart of study selection. PRISMA, Preferred Reporting Items for Systematic reviews and Meta-Analyses.

Characteristics of included studies

Trial characteristics are summarised in table 1. All six trials were conducted in the USA. Five were cluster randomised[28] (Poeran J, unpublished data, 2024)[39 40 42] and one was randomised at the patient level.[41] Sample sizes ranged from 767 to 21 331 clinical encounters, with five trials having >1000 encounters. The median age of patient participants ranged from 32 to 73 years old. Follow-up periods ranged from 20 weeks[28] to 18 months.[39 40] The number of clinicians included ranged from 21[42] to 490.[39] Two trials were based in emergency departments,[28 39] one in primary care,[39] one in dentistry,[40] two in hospitals and health centres, (Poeran J, unpublished data, 2024)[41] and one in radiology oncology.[42]

Description of the types of default nudges

Default nudges could be grouped into four intervention subgroups: default quantity,[28 39 40] default dose, (Poeran J, unpublished data, 2024) opt-out default[41] and default frequency.[42]

Default quantity

Three trials used defaults by changing the default quantity of tablets in the electronic medical system.[28 39 40] The preset default tablet quantity for prescriptions of targeted medicines was changed. Only the default quantity of tablets changed, the medication dose remained unchanged. One trial by Montoy and colleagues[28] changed the default quantity of tablets for opioid prescriptions for patients discharged from the emergency department. Relevant defaults of 5, 10 and 12 tablets were included. The control condition introduced a null default, so clinicians would need to specify the quantity for every order. Two trials by Bachhuber and colleagues changed the default quantity of tablets for opioid prescriptions to 10 tablets in primary and emergency care[39] and to 5 and 10 tablets in dentistry clinics.[40] Defaults were compared with usual care, or the existing system defaults, which was most commonly null or 30 tablets depending on the site.

Opt-out default

One trial evaluated an opt-out default. Moehring and colleagues[41] identified patients with suspected sepsis who were eligible for antibiotic discontinuation. In the intervention condition, study team members contacted eligible patients' clinician and informed them that their patient passed a safety screen, and antibiotics would be stopped unless they opted out. Here, the default was antibiotic discontinuation for eligible patients. This was compared with usual care where treating clinicians received no external prompt.

Default dose

One trial by Poeran and colleagues (Poeran J, unpublished data, 2024) reduced the default dose for eight medications considered high-risk for inpatients aged 65 and older for hospitals randomised to the intervention condition. For example, the default dose for trazodone was lowered from 50 mg to 25 mg. The lower dose default nudge was compared with usual care (existing dose settings).

Default frequency

One trial changed the default frequency of medical interventions. Sharma and colleagues[42] updated the default frequency of imaging for palliative care patients at radiation oncology clinics. The default imaging frequency was set to 'no daily imaging' within the electronic health system to reduce imaging of patients at each treatment appointment. Authors defined 'daily imaging' to be imaging provided in ≥80% of appointments and considered this to be unnecessary and an example of overuse.

Risk of bias and certainty of evidence assessment

Risk of bias assessments are presented in online supplemental table 5. Two trials had low risk of bias in all domains.[41 42] GRADE certainty of evidence ranged from moderate to very low certainty, with most comparisons being assessed as low certainty (six of nine comparisons) (online supplemental table 6).

Effectiveness of default nudges at reducing overuse of tests and treatments

The range of effect estimates is presented in four subgroups based on the outcome subgroup: reducing overuse of opioid medicines,[28 39 40] reducing overuse of antibiotics,[41] reducing overuse of high-risk medications (Poeran J, unpublished data, 2024) and reducing overuse of imaging.[42]

Compared with usual care, default nudges demonstrated a reduction in overuse in three trials,[39 41 42] mixed results in two trials[28 40] and no effect in one trial (table 2). (Poeran J, unpublished data, 2024) All trials used the electronic health system to implement the default nudge. There was limited reporting of adverse events among trials (four of six trials).(Poeran J, unpublished data, 2024)[39–41] No trial measured patient-reported outcomes (eg, pain, disability or satisfaction). We presented effect estimates in a forest plot (figure 2) with standardised effect size calculations presented in online supplemental table 7.

Reducing overuse of opioid medicines

Default quantity nudges led to large reductions in overuse of large packs of opioids in two of three studies. Our subgroup meta-analysis found that a default of 10 tablets led to a pooled risk difference of −14.3% (95% CI −51.4% to +22.9%, random effects model, 3 trials, 18 186 encounters, very low certainty evidence) across emergency, dentistry and primary care settings. Substantial heterogeneity was observed (I^2=97%, 95% CI 94.1% to 98.5%).

Table 1 Study characteristics

Author name, study design, country reference	Setting and targeted practice considered to be overuse	Intervention condition	Control condition	Patient population	Clinicians included	Type of default	Brief description of intervention
Montoy 2020, cluster crossover randomised controlled trial, USA[28]	Two emergency departments Overuse practice targeted: opioid prescriptions of>12 tablets	Three intervention conditions: ► 5-tablet default ► 10-tablet default ► 12-tablet default	One control condition: ► Null default	All emergency department patients receiving an opioid prescription at discharge	104 healthcare professionals in the emergency department—including physicians, nurse practitioners and physician assistants	Default quantity	Implemented a default quantity for opioid medications of 5 tablets, 10 tablets and 12 tablets for all opioid medications, irrespective of dose
Bachhuber 2021, parallel cluster randomised controlled trial, USA[39]	32 primary care practices and four emergency departments Overuse practice targeted: opioid prescriptions of >10 short acting opioid tablets for acute pain	One intervention condition: ► 10-tablet default	One control condition: ► Usual care (most commonly blank or 30 tablets)	Patients ≥18 years, receiving a new opioid prescription (no opioid analgesics prescribe 6 months prior), no cancer diagnosis 1 year prior	490 prescribers were from primary and emergency care, internal and family medicine	Default quantity	Implemented a default quantity for all short acting opioid medications of 10 tablets, irrespective of dose
Bachhuber 2023, parallel cluster randomised controlled trial, USA[40]	Three dentistry clinics Overuse practice targeted: opioid prescriptions of >10 opioid tablets	Two intervention conditions: ► 5-tablet default ► 10-tablet default	One control condition: ► Usual care (default quantity most commonly null or 30 tablets)	Patients ≥18 years, without cancer diagnosis	34 clinicians including dentists, oral maxillofacial surgery specialists and trainee dentists	Default quantity	Implemented a default quantity for all short acting opioid medications of 5 tablets or 10 tablets, irrespective of dose
Moehring 2023, patient level randomised controlled trial, USA[41]	10 acute care hospitals Overuse practice targeted: continuing antibiotics in people who are safe to deescalate	One intervention condition: ► Opt-out of default of antibiotic discontinuation	One control condition: ► Usual care (null default)	Patients ≥18 years in non-intensive care units with previously suspected sepsis, eligible for antibiotic discontinuation	Physicians, nurse practitioners, trainees and physicians' assistants in medicine, surgery, infectious diseases and surgery (number not reported)	Opt-out default	Clinicians were notified when their patients were safe for antibiotics de-escalation, and antibiotics would be discontinued unless they opted out
Poeran (unpublished), cluster crossover randomised trial, USA[43–45]	10 hospitals and health centres Overuse practice targeted: prescriptions of high-risk medications for older hospitalised populations	One intervention condition: ► Lower default dose	One control condition: ► Usual care (usual default dose)	Admitted patients ≥65 years	Any prescribing clinician (number not reported).	Default dose	Implemented a lower default dose for eight high-risk medicines
Sharma 2019, stepped-wedge cluster trial, USA[42]	Five radiation oncology practices Overuse practice targeted: daily imaging for palliative radiotherapy	One intervention condition: ► Reduced default frequency for imaging	One control condition: ► Usual care (daily imaging, imaging in ≥80% of treatments)	Patients ≥18 years with bone, soft tissue or brain metastases receiving three-dimensional conformal radiotherapy	21 physicians providing palliative radiotherapy	Default frequency	Implemented a default prescription template order in the electronic health system that specified no daily imaging during palliative radiotherapy

Table 2 Summary of the effect of default nudges on overuse of tests and treatments

Author name, setting (reference)	Default nudge—brief description	Primary overuse outcome, outcome measure, timepoint	N (%) episodes overuse, control	N (%) episodes overuse, intervention	Risk difference (95% CI)	Certainty of evidence	Summary results
Montoy 2020, Emergency departments[28]	Default quantity—Compared default quantity of null (control), 5 tablets, 10 tablets and 12 tablets for all opioids, irrespective of dose.	Overuse of opioid medicines, proportion of prescriptions written for >12 opioid tablets, 20 weeks.	Null 198/415 (47.7)	5 tablets 438/1020 (42.9)	5 tablets −4.8% (−10% to 0.9%)	5 tablets Very low certainty	The 5-tablet and 12-tablet default significantly reduced opioid prescriptions for >10 tablets compared with the null default. The 10-tablet default had no significant effect.
			Null 198/415 (47.7)	10 tablets 312/620 (50.3)	10 tablets +2.6% (−3.6% to +8.8%)	10 tablets Very low certainty	
			Null 198/415 (47.7)	12-tablets 229/969 (23.6)	12 tablets −24.1% (−30.0% to −19.0%)	12 tablets Low certainty	
Bachhuber 2021, Primary care and emergency departments[39]	Default quantity—Compared default quantity of 10 tablets with usual care (usual default most commonly blank or 30 tablets) for short acting opioids, irrespective of dose.	Overuse of opioid medicines, proportion of prescriptions written for >10 opioid tablets, 18 months.	4900/7651 (64.0)	2826/6163 (45.9)	−18.1% (−20.0% to −16.6%)	Low certainty	The 10-tablet default significantly reduced the percentage of opioid prescriptions for >10 tablets, leading to a lower total number of tablets and lower MME.

Continued

Table 2 Continued

Author name, setting (reference)	Default nudge—brief description	Primary overuse outcome, outcome measure, timepoint	N (%) episodes overuse, control	N (%) episodes overuse, intervention	Risk difference (95% CI)	Certainty of evidence	Summary results
Bachhuber 2023, Dentistry[40]	Default quantity—Compared default quantity of 5 tablets or 10 tablets with usual care (usual default most commonly blank or 30 tablets) for all short acting opioids, irrespective of dose.	Overuse of opioid medicines, proportion of prescriptions written for>10 opioid tablets, 18 months.	Usual care 779/1327 (58.7) Usual care 779/1327 (58.7)	5 tablets 811/1221 (66.4) 10 tablets 643/2010 (32.0)	5 tablets +7.7% (+4.0% to +11.0%) 10 tablets −26.7% (−30.1% to −23.4%)	5 tablets Low certainty 10 tablets Low certainty	The 5-tablet default increased the proportion of prescriptions for >10 tablets, however, there was no significant difference in the total tablets or MME compared with the control at 30 days. The 10-tablet default significantly reduced the proportion of prescriptions for >10 tablets and maintained a reduction in the total number of tablets and MME at 30 days compared with the control.
Moehring 2023, Acute care hospitals[41]	Opt-out default—Clinicians were notified that their patients were eligible to stop antibiotics, and they'd be discontinued unless they opted-out. Compared with usual care. Irrespective of dose.	Overuse of antibiotics, proportion of antibiotics prescribed, 6 months.	324/384 (84.4)	301/383 (78.6)	−5.8% (−11.0% to −0.3%)	Low certainty	Opt-out default led to a significant reduction in antibiotic overuse. Infectious disease, surgery and trainee clinicians were less likely to agree to discontinue antibiotics.
Poeran unpublished, Hospitals and health clinics	Default dose—Compared a lower default dose for eight high-risk medicines with usual care, irrespective of tablet quantity.	Overuse of high-risk medications, proportion of prescriptions not remaining with the default dose, 24 weeks.	1240/1801 (68.9)	1122/1686 (66.6)	−2.3% (−5.4% to +0.8%)	Low certainty	No effect.

Continued

Table 2 Continued

Author name, setting (reference)	Default nudge—brief description	Primary overuse outcome, outcome measure, timepoint	N (%) episodes overuse, control	N (%) episodes overuse, intervention	Risk difference (95% CI)	Certainty of evidence	Summary results
Sharma 2019, Radiology oncology clinics[42]	Default frequency—Compared a default prescription template order in the electronic health system that specified no daily imaging during palliative radiotherapy, with usual care.	Overuse of imaging, proportion of radiotherapy courses with daily imaging (imaging in ≥80% of treatments), 8 months.	463/679 (68.2)	165/509 (32.4)	−35.8% (−41.0% to −3.00%)	Moderate certainty	The default intervention led to a significant reduction in daily imaging.

MME, morphine milligram equivalent.

The most effective default nudge at reducing opioid overuse occurred in dentistry clinics.[40] Compared with usual care (existing defaults typically 30 tablets or null), a 10-tablet default reduced overuse of large packs of opioids (>10 tablets) from 58.7% to 32.0%, risk difference −26.7% (95% CI −30.1% to −23.4%, 1 trial, 3337 encounters, low certainty evidence). Compared with the control, authors reported that the 10-tablet default resulted in a lower number of tablets prescribed, adjusted difference in difference (aDID) −3.3 tablets (95% CI −5.9 to −0.7 tablets) and a lower total MME prescribed, aDID −14.1 MME (95% CI −27.8 to −0.4 MME). At 30 days, there were more reorders compared with the control, aDID 3.3 percentage points (95% CI 0.2 to 6.4), but the total number of tablets was not significantly different, aDID −3.3 tablets (95% CI −5.6 to 1.0 tablets) and MME remained reduced, aDID −15.7 MME (95% CI −28.1 to −3.3 MME).

The least effective default nudge at reducing opioid overuse was from the same trial in dentistry clinics.[40] Compared with usual care, a 5-tablet default increased overuse of large packs of opioids (>10 tablets) from 58.7% to 66.4%, risk difference +7.7% increase in overuse (95% CI +4.0% to +11.0%, 1 trial, 2548 encounters, low certainty evidence).[40] Authors reported no difference in total number of tablets, aDID −0.2 tablets (95% CI −0.7 to 0.2) or MME prescribed, aDID 2.4 MME (95% CI −1.4 to 6.5 MME). At 30 days, there were more reorders compared with the control, aDID 2.6 percentage points (95% CI 0.2 to 4.9), but no difference in the total number of tablets, aDID 0.1 tablets (95% CI −0.7 to 0.9) or total MME prescribed, aDID 3.1 MME (95% CI −5.1 to 11.2), respectively. All trials targeting opioid overuse have been presented in a separate forest plot (online supplemental figure 1).

Reducing overuse of antibiotics

One trial targeted overuse of antibiotics in patients with suspected sepsis, who were identified as safe to discontinue antibiotics.[41] As a result of the opt-out default, antibiotic continuation reduced in the intermediate term, from 84.4% to 78.6%, risk difference −5.8% (95% CI −11.0% to −0.3%, 1 trial, 767 patients, very low certainty evidence). Minor differences in safety outcomes were reported, with the intervention group reporting fewer events for *Clostridioides difficile* infection, deep vein thrombosis, intensive care unit admission, haemodialysis and death.

Reducing overuse of high-risk medications

One trial showed that compared with usual care, reducing the default dose for eight high-risk medications for older adults in hospital had no effect. (Poeran J, unpublished data, 2024) Prescriptions for higher doses of targeted high-risk medications were 68.9% in the control group and 66.6% in the intervention

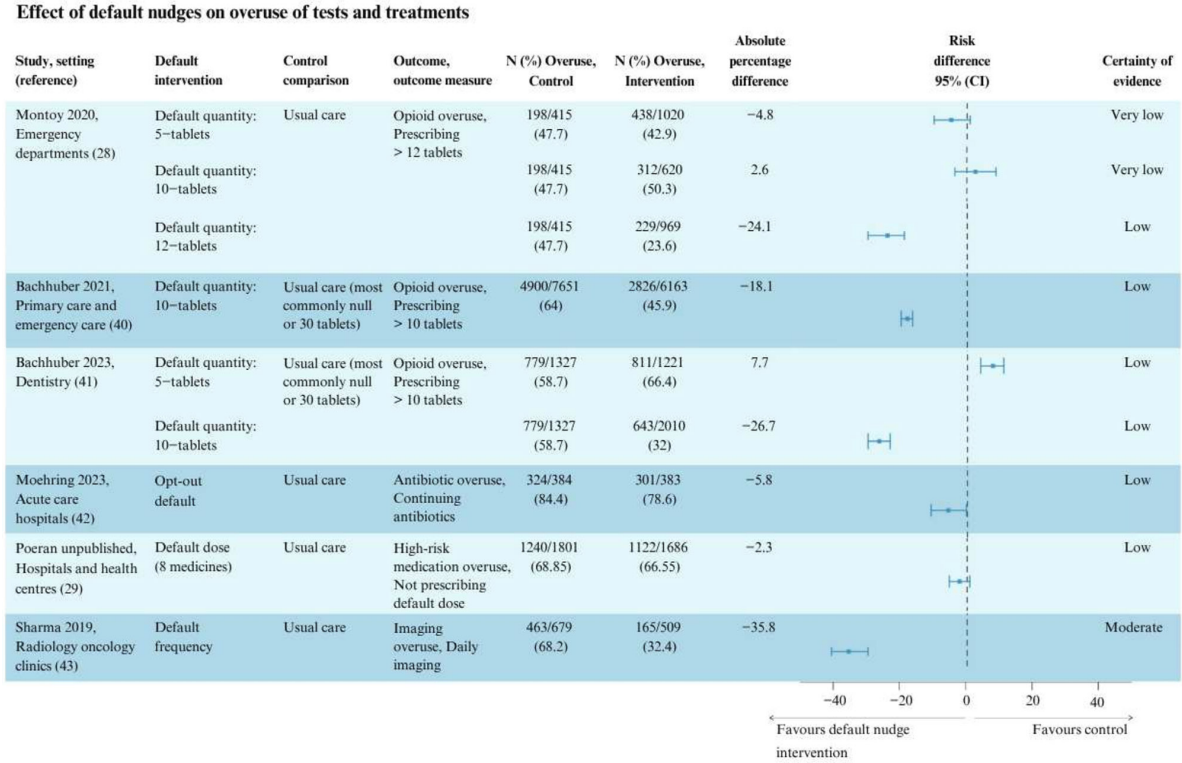

Figure 2 Forest plot showing effects of defaults on the proportion of targeted tests or treatments considered to be overuse. Standardised effect sizes do not account for clustering.

group, risk difference of −2.3% (95% CI −5.4% to 0.8%, 1 trial, 3487 encounters, very low certainty evidence). There were no significant differences in readmissions at 30 days, inpatient falls or length of hospital. (Poeran J, unpublished data, 2024)

Reducing overuse of imaging

One trial randomised oncology practices to receive a prescription template order in the electronic health system that specified no daily imaging as the default frequency for patients receiving palliative radiotherapy.[42] It found that in comparison to usual care, the intervention substantially reduced daily imaging in the intermediate term.[42] Providing imaging in ≥80% of treatments was reduced from 68.2% to 32.4%, risk difference was −35.8% (95% CI −41.0% to −30.0%, 1 trial, 1188 encounters, moderate certainty evidence).[42] This was the largest reduction in overuse across all trials.

DISCUSSION

Principal findings

We found limited evidence on the effects of default nudges to reduce overuse of healthcare. Effects were inconsistent and appeared to vary widely depending on clinical context and default settings. Default nudges showed positive results in three trials, mixed results in two and no effect in one. A default for fewer tablets may reduce overuse of large packs of opioids. It is also unclear if an opt-out default nudge can reduce antibiotic overuse, or if a lower default dose can reduce overuse of high-risk medications for older patients. Reducing the default frequency for imaging probably causes large reductions in overuse of daily imaging for patients undergoing palliative radiotherapy. Certainty of evidence ranged from very low to moderate certainty, with most comparisons being assessed as low certainty (five of nine comparisons).

Most trials examined the effect of default nudges on the overuse of medicines, particularly opioids. Default quantity nudges for opioid medications caused large reductions in overuse in some trials;[28 39 40] however, results were not consistent. For instance, in one trial a 5-tablet default increased overuse of large opioid prescriptions in dentistry,[40] whereas the same default reduced overuse in emergency care.[28]

Of the six included trials, only four measured adverse events or harms, and none included patient-reported outcomes. While health service measures are useful for evaluating the impact of default nudges on clinician behaviour, they do not capture patient experience. The absence of patient-reported outcomes limits our ability to determine whether patients ultimately benefited from these interventions. For example, a default nudge may successfully reduce overuse but may also result in undertreatment, persistent symptoms or

worse clinical outcomes that are not captured through administrative or service-level data alone.

Interpretation of findings

The direction and magnitude of effects associated with default nudges on overuse varied across trials. Existing behavioural evidence suggests that default nudges are more likely to be accepted when (1) decisions are difficult, (2) decision-makers have no strong prior preferences and/or (3) the perceived consequences are small.[12 48] These decision features may help explain why some default nudges reduced overuse and others did not. For instance, setting the default frequency of imaging for patients receiving palliative radiotherapy as 'no daily imaging' led to large reductions in overuse of imaging.[42] In this clinical context, clinicians may have had no strong prior preferences and judged the risk of harm from accepting the default as minimal, so they were more likely to accept the new default.

The perceived consequences of a default nudge may influence the likelihood of success. A 10-tablet default led to large reductions in opioid overuse in dentistry, suggesting that 10 tablets may have been judged as appropriate, with minimal risk of harm for this patient population. In contrast, in the same setting, the 5-tablet default led to an increase in prescriptions for larger packs of opioids compared with usual care. This suggests that the consequences (poorer patient outcomes, prescription reorders) associated with a 5-tablet prescription for these patients were too high for clinicians to accept the default. Yet the same default quantity of 5 tablets led to a reduction in opioid overuse in emergency care settings. In this context, clinicians may have considered a 5-tablet prescription to be appropriate for most patients in emergency care settings. The success of a default nudge might therefore depend on how these decision features differ between clinical contexts.[12]

Strengths and limitations

This systematic review has several strengths compared with previous reviews. First, our review focused specifically on default nudges aimed at reducing overuse of tests and treatments in healthcare. This allowed us to identify relevant gaps in evidence while considering the influence of context on behaviour change.[49] Second, unlike previous reviews, we focused on trials of default nudges evaluated independently of other interventions such as education.[11 21 24] This approach allowed for a clearer interpretation of default nudge effects independent of potentially confounding factors. Finally, prior reviews did not provide standardised estimates of effect across different clinical contexts and did not assess the certainty of evidence.[11 20 21 24] Standardising effect sizes across trials allowed us to make meaningful comparisons of magnitude and direction of effects between trials and nudge interventions.[26 50]

Our review also has some limitations. First, we were unable to evaluate the risk of publication and selection biases due to the small number of trials.[38] However, modelling suggests that more recent trials may have lower risk of publication bias.[51] As our oldest trial was published in 2019, the risk of publication bias may therefore be comparatively lower. The mixed results of the included trials also provide evidence against publication bias. Second, it was not possible to account for clustering in our calculation of standardised effect sizes, which can lead to artificially narrow CIs.[36] However, this was only the case for one trial.[40] Finally, using the proportion of overuse as our primary outcome measure provides only part of the picture of health service provision. For example, in the context of opioid overuse, it is possible that while the proportion of overuse of large-pack opioid prescriptions might decrease, the total number of opioid prescriptions provided over the same period might increase. However, in the included trials that reduced the proportion of large packs of opioids, the total quantity also remained unchanged or decreased.

Key areas for research, policy and practice

This is a rapidly evolving field of inquiry. Until recently, the evidence has been largely from observational studies, with randomised trials only emerging in the last 6 years. While clinician-directed default nudges have potential to improve care at scale, they may also cause harm at scale. These clinician-directed interventions must be subjected to the same scrutiny as other clinical interventions that can impact patient outcomes. The recent adoption of randomised methodologies suggests a shift in the right direction, and there is specific guidance available for clinicians and trialists.[52 53]

Additionally, future trials could make several improvements to improve the evidence base and ensure patient safety. First, default nudges should be tailored to the healthcare setting, patient need and clinician preferences.[12 49 54] A single clinically appropriate default may not be appropriate for an entire patient cohort, but triage categories or diagnosis labels could be used to assign individualised defaults to subgroups of patients.[55 56] Second, clinicians, policymakers and/or researchers should evaluate the independent effect of default nudges through high-quality randomised trials, rapid randomised testing or pseudo-randomisation[52 53] to reduce risk of bias and improve the certainty of evidence.[57 58] Finally, evaluations of nudges must also include patient outcomes to ensure that nudges do not cause harm.[59 60]

CONCLUSION

Current trials of clinician-directed default nudges demonstrated mixed effects on overuse; while some interventions showed significant reductions in overuse, others unexpectedly increased overuse. With few randomised trials, limited and mostly low certainty evidence, it is uncertain if, or under what conditions, defaults are effective at improving healthcare. To ensure defaults are safe and effective for patients, future trials should consider tailoring defaults, using randomised methods and examining the effect on adverse events and patient outcomes.

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Contributors GA led this systematic review under the supervision of AT and CMPJ. AT and CMPJ had full access to all the data in the study and confirm the integrity and the accuracy of the data analysis. Concept and design: GA led the protocol development with substantial methodological and subject matter input from AT, GEF, TCH, JAL, CM and JS. Acquisition, analysis or interpretation of data: GA conducted the database and clinical trial registry searches, with support and secondary registry searched by CMPJ. Two reviewers (GA and CMPJ, GEF or AT) independently screened titles and abstracts to assess eligibility. Full texts were reviewed in duplicate (GA and CMPJ, GF, AT or RC). Two reviewers independently extracted study characteristics and outcome data for all reported outcome timepoints (GA and CMPJ, GEF, RC). Any disagreements were resolved by discussion or with a third independent reviewer (CM). Risk of bias and certainty of evidence assessments were conducted by GA and CJ, with disagreements resolved with AT. GA, AT and RC conducted standardisation calculations. GA conducted meta-analysis with appraisal by AT and CMPJ. GA, AT, CMPJ and CM contributed to the interpretation of the data. Drafting of the manuscript: GA led the drafting of the manuscript under the supervision and mentorship of AT, CMPJ and CM. Critical revision of the manuscript for important intellectual content: all authors reviewed the final manuscript and provided valuable input and revisions.

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CHAPTER Five: Multiple suggested care alternatives and decision-making of primary care physicians: a randomized clinical trial

Chapter Five presents a randomised controlled trial examining the effect of the number of care alternatives in suggested alternative nudges on primary care physician decisions to remain with a lower value care option or replace it with a preferred alternative.

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Multiple Suggested Care Alternatives and Decision-Making of Primary Care Physicians
A Randomized Clinical Trial

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Abstract

IMPORTANCE Decision support alerts or nudges are used in health care settings to guide clinical decisions toward preferred care. However, it is unclear whether the number of alternatives offered leads to suboptimal decisions.

OBJECTIVE To determine the effect of presenting two or more appropriate treatment alternatives, compared to one alternative, on care decisions.

DESIGN, SETTING, AND PARTICIPANTS This randomized clinical trial conducted from May 3 to May 8, 2024, included primary care physicians (PCPs) practicing in the US who were recruited from the Qualtrics research network and were randomly assigned 1:1 to review 2 clinical scenarios. Physicians in the control group were presented with 1 appropriate treatment alternative for each scenario and those in the intervention group were presented with 2, 3, or 4 treatment alternatives.

INTERVENTION Physicians were presented with 2 clinical scenarios—one on surgery referral for hip osteoarthritis and one on opioid prescribing for back pain—and asked to decide whether to remain with an existing management plan or to select an appropriate alternative.

MAIN OUTCOMES AND MEASURES The primary outcome was the proportion of PCPs choosing an alternative over the current management plan. In the secondary analysis, odds ratios (ORs) with 95% CIs were calculated to measure the effect of each additional alternative added to the choice set on decisions in the intervention group (ie, increasing from 2 to 3 to 4).

RESULTS Among 402 physicians (231 [57.5%] with <10 years of clinical experience), 201 identified as men (50.0%) and were from 46 US states, with 196 (49.5%) from urban or metropolitan areas. Of these, 200 were assigned to the control group (1 alternative across 2 clinical scenarios [400 total treatment decisions]) and 202 to the intervention group (≥2 alternatives across 2 clinical scenarios [404 total treatment decisions]). Physicians in the intervention group had significantly higher odds of choosing an appropriate alternative (251 of 404 treatment decisions [62.1%]) compared with those in the control group (176 of 400 treatment decisions [44.0%]) (adjusted OR, 1.90; 95% CI, 1.09-3.30; *P* = .02). The effect was stronger in the opioid prescribing scenario (30.5% [61 of 200 treatment decisions] vs 56.4% [114 of 202 treatment decisions], OR, 2.95; 95% CI, 1.96-4.45) than the surgery referral scenario (57.5% [115 of 200 treatment decisions] vs 67.8% [137 of 202 treatment decisions], OR, 1.56; 95% CI, 1.04-2.34). Increasing the number of alternatives beyond 2 did not increase the effect.

(continued)

Key Points

Question Does offering multiple appropriate treatment alternatives affect the odds of primary care physicians choosing an alternative over the current care plan?

Findings In this randomized clinical trial of 402 primary care physicians, offering 2 or more appropriate alternatives significantly increased the odds that physicians would choose an alternative (62%) compared with those offered only 1 alternative (44%).

Meaning Contrary to prior studies suggesting status-quo bias, in this trial, presenting multiple appropriate alternatives in decision support alerts increased the odds that physicians would choose an alternative; indicating that presenting multiple alternatives may improve clinical decision-making and reduce unwarranted variation in health care.

+ Visual Abstract

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

Abstract (continued)

CONCLUSIONS AND RELEVANCE In this randomized clinical trial of 402 PCPs, we found that presenting 2 or more appropriate treatment alternatives increased the odds that physicians would choose an alternative. This challenges earlier suggestions that physicians experience status-quo bias when they are offered more than 1 alternative. Decision support alerts may be more effective when offering multiple appropriate alternatives, rather than only 1.

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Introduction

Unwarranted health care variation is the inconsistency of clinical care that cannot be explained by patient symptoms or preferences.[1,2] Health care variation can include overuse of tests and treatments that do not offer any benefit to patients.[3] It can also include the underuse of care that would benefit patients.[4] Unwarranted health care variation represents a risk to patient safety and the quality of health care internationally.[5,6] A common example is the overuse of opioid analgesics and underuse of safer, more effective alternatives, such as nonsteroidal anti-inflammatory drugs (NSAIDs), for patients with low-back pain in primary care.[7-9] Despite efforts to reduce unwarranted health care variation through dissemination of guidelines, public awareness campaigns, and quality improvement projects, the problem persists.[5,10-12]

Computerized interventions are increasingly implemented in health care settings to improve care.[13,14] These interventions can include decision-support tools, best-practice alerts, and suggested alternative nudges.[15,16] Suggested alternative interventions, in which clinicians are provided a list of treatment alternatives at the point of care, have been used to reduce overuse of antibiotics in primary care[16] and opioids in emergency departments.[17] Such interventions may support decision-making by disrupting habitual prescribing patterns, increasing the salience of appropriate alternatives, and signaling which treatment is recommended.[17-19]

The effectiveness of these interventions in improving care may depend on the number of appropriate alternatives provided. In a highly cited experiment, Redelmeier and Shafir[20] suggested that providing 2 care alternatives instead of 1 led physicians to paradoxically remain with an existing management plan. This result was striking because it violated normative choice theory or the Luce Choice Axiom, which states that the introduction of a third alternative should not increase the selection of existing options or the status quo.[21,22] Redelmeier and Shafir[20] concluded that providing multiple alternatives creates decision difficulty among physicians, triggering a cognitive bias, known as status-quo bias. The implication was that decision supports should limit the number of options presented to clinicians.

While the study by Redelmeier and Shafir[20] has been influential in shaping our understanding of clinical decision-making, a more recent study[23] could not replicate the original findings. Restricting care alternatives shown to clinicians based on limited or outdated evidence could lead to suboptimal care.[24-26] Since the original study, there have been substantial advances in research methods, insights on decision-making, and the influence of electronic health systems in clinical decision-making.[27-30] As such, interventions to address unwarranted health care variation require the latest evidence, supported by rigorous scientific methods, to effectively improve health care quality and safety.[31,32]

This randomized clinical trial aimed to determine the effect of the number of appropriate treatment alternatives in a choice set on clinical decision-making. Specifically, we investigated whether providing 2 or more alternatives influenced the odds that primary care physicians (PCPs) would select an alternative treatment or remain with the existing (status-quo) management plan.

Methods

In this randomized clinical trial, the hypothesis, treatment conditions, and allocation were concealed from participants. After reading the participant information on the online form, participants provided written consent by clicking "yes, I consent." The Sydney Local Health District Human Ethics Committee approved this trial. The ethics approved study materials are available in the eMethods 1 in Supplement 1, and the trial protocol is provided in Supplement 2. We followed the Consolidated Standards of Reporting Trials (CONSORT) and the Template for Intervention Description and Replication (TIDieR) reporting guidelines.

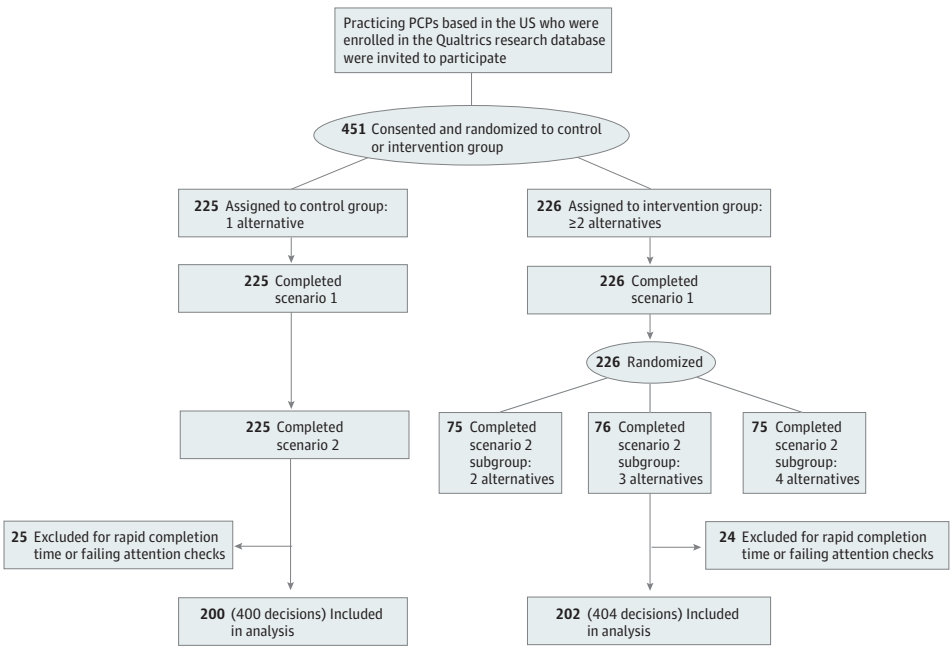
Participants

Practicing PCPs in the US who were registered with the Qualtrics research network were invited via email to participate in a survey. Qualtrics is a large online platform that connects researchers with participants. Physicians who completed the clinical scenarios received compensation (equivalent to approximately $22) through their Qualtrics membership.

Randomization

Physicians were randomly assigned 1:1 to the control or intervention condition (**Figure**) using computerized randomization via the Qualtrics platform. Participant flow and randomization were programmed by trial investigators with support from a Qualtrics data manager. Investigators were blinded to the group allocation and responses until the sampling was complete, and the survey was closed. To ensure data integrity, the independent data manager removed responses that did not meet their data-quality standards (eg, rapid completion time or failed attention checks) before providing the final dataset for analysis.[33]

Figure. Participant Randomization



PCP indicates primary care physician.

Procedure

Physicians were presented with 2 clinical scenarios commonly seen in primary care. Each scenario—one about a surgery referral for hip osteoarthritis, and the other about opioid prescribing for lower-back pain—involved a decision about whether to remain with an existing management plan or to select an alternate plan. In the control condition, physicians received 1 appropriate treatment alternative. In the intervention condition, physicians could receive 2, 3, or 4 appropriate alternatives.

Interventions

The clinical scenarios were designed during protocol development (Supplement 2) with the research team that included PCPs, behavioral economists, and investigators with expertise in research methods. Guidance on designing experimental vignette studies to identify factors of health care variation was followed.[34] The scenarios were carefully designed to assess whether the number of treatment alternatives influenced care decisions.[35-37]

Key design elements were implemented. First, the scenarios and treatment alternatives were designed to have comparable trade-off complexity.[35] The scenarios included details about the patient and clinical situation to ensure that choosing to remain with the current care plan or an alternative could both be considered reasonable clinical decisions. Treatment alternatives were limited to NSAIDs with similar risk-benefit trade-offs and dose frequency to ensure no option was obviously superior or inferior. As such, other guideline concordant care options, such as exercise, were not included. This allowed us to isolate the effect of the number of alternatives on decision-making, rather than measuring physician preferences for specific treatments. Second, to further control for physician preferences, alternatives were randomly selected from a longer list of appropriate NSAID alternatives for each participant (eMethods 1 in Supplement 1). Third, physicians were asked to assume there was no difference in financial costs for any option and there was no single right answer. Scenarios and treatment alternatives were considered credible, relevant, and clear by clinician investigators.

Scenario 1 featured a patient with chronic hip pain and osteoarthritis and replicated the Redelmeier and Shafir[20] study, with updates to ensure clinical relevance in 2024 (eg, drug names, patient's profession). In this scenario the patient had been seeing a physiotherapist and walked daily. They had tried 1 NSAID but stopped due to limited efficacy. The existing management plan (or status-quo option) in this scenario was to refer the patient to an orthopedic surgeon, without trying a new NSAID. The alternative options presented were to continue with the referral and also start the patient on a new NSAID. Control physicians were presented with 1 NSAID alternative and intervention physicians were presented with 2 NSAID alternatives (eTable 1 in Supplement 1).

Scenario 2 featured a patient with chronic low-back pain. In this scenario the patient had been managing their back pain with physiotherapy and regular exercise over the past few months. Approximately 2 weeks ago the patient received a 3-day supply of an opioid analgesic (oxycodone) to help manage a flare up. In this scenario the patient had requested another 3-day supply of oxycodone but, when the physician initiated the order, an alert was triggered, suggesting that they consider an NSAID instead. The status-quo option was to continue with the opioid analgesic, and the alternative was to try an NSAID. Control physicians were presented with 1 NSAID alternative and intervention physicians were presented with 2, 3, or 4 NSAID alternatives (eTable 2 in Supplement 1).

Outcomes

The primary outcome was the proportion of PCPs who chose an alternative treatment option. The secondary outcome was the effect of increasing the number of alternatives to 3 and 4 alternatives on clinical decision-making. Baseline characteristics were collected after physicians completed the clinical scenarios (**Table 1**).

Statistical Analysis

The study by Redelmeier and Shafir[20] observed an absolute difference of 19% between groups. To detect a 14% difference with 80% power and a 2-sided α = .05, we required 198 physicians per condition completing 2 scenarios. Our primary analysis used a binary logistic regression interaction model with generalized estimation equations (GEE) to estimate the effect of the intervention on the proportion of clinicians choosing an alternative (eMethods 1 in Supplement 1). Our GEE analysis accounted for within participant clustering (as each physician completed 2 scenarios) and interaction effects between the group and the clinical scenario (eMethods 2 in Supplement 1). Effect sizes were presented as odds ratios (OR) with 95% CIs. A 2-sided $P < .05$ was considered statistically significant. As a secondary exploratory analysis, we estimated unadjusted effects in the total sample and in each scenario using 3 univariate logistic regression models. We also calculated the number and proportion choosing an alternative in the subgroups presented with 2, 3, or 4 alternatives. Statistical analyses were conducted using R, version 4.3.2 (R Project for Statistical Computing).

Results

Of the 402 physicians (231 [57.5%] with <10 years of clinical experience; 171 [42.5%] with ≥10 years clinical experience) included in the analyses, 199 identified as women (49.5%), 201 identified as men (50.0%) and 2 preferred not to say (0.5%). Participants were from 46 US states, with 196 (49.0%) from urban or metropolitan areas (Table 1). A total of 451 physician participants were randomized and completed the scenarios; however, 49 responses (10.9%) had rapid completion time or failed data

Table 1. Participant Characteristics

Characteristic	Participants, No. (%)		
		Control group	Intervention group
	All (n = 402)	1 Appropriate treatment alternative (n = 200)	≥2 Appropriate treatment alternatives (n = 202)
Gender			
Women	199 (49.5)	116 (58.0)	83 (41.1)
Men	201 (50.0)	84 (42.0)	117 (57.9)
Prefer not to say	2 (0.5)	0	2 (1.0)
Years in clinical practice			
<5	88 (21.9)	39 (19.5)	49 (24.3)
5-9	143 (35.6)	67 (33.5)	76 (37.6)
10-14	98 (24.4)	60 (30.0)	38 (18.8)
15-19	49 (12.2)	25 (12.5)	24 (11.9)
≥20	24 (6.0)	9 (4.5)	15 (7.4)
Proportion of working hours in clinical practice, %			
≤25	68 (16.9)	34 (17.0)	34 (16.8)
26-50	132 (32.8)	68 (34.0)	64 (31.7)
51-75	155 (38.6)	81 (40.5)	74 (36.6)
>75	47 (11.9)	17 (8.5)	30 (14.9)
Time instructing medical students, h/wk			
≤5	116 (28.9)	47 (23.5)	69 (34.2)
6-10	164 (40.8)	81 (40.5)	83 (41.1)
11-15	95 (23.6)	61 (30.5)	34 (16.8)
≥16	27 (6.7)	11 (5.5)	16 (7.9)
Rurality			
Rural	52 (12.9)	28 (14.0)	24 (11.9)
Suburban	154 (38.3)	76 (38.0)	78 (38.6)
Urban or metropolitan	196 (48.8)	96 (48.0)	100 (49.5)

integrity checks and were excluded (Figure). Of these participants, 200 physicians (with 400 decisions in total) were assigned to the control group and 202 (with 404 decisions in total) were assigned to the intervention group. Physicians completed the scenarios between May 3 and 8, 2024.

Primary Outcome

Physicians had significantly higher odds of choosing a treatment alternative when presented with 2 or more appropriate alternatives rather than just 1 (44.0% [176 of 400 treatment decisions] in control vs 62.1% [251 of 404 treatment decisions] in intervention; unadjusted OR, 2.09; 95% CI, 1.58-2.77) (**Table 2**). The GEE model, which accounted for both clustering and interaction effects, estimated an adjusted OR of 1.90 (95% CI, 1.09-3.30; *P* = .02), indicating a statistically significant effect of the intervention. The intervention had a larger effect in the opioid prescribing scenario (30.5% [61 of 200 treatment decisions] vs 56.4% [114 of 202 treatment decisions]; unadjusted OR, 2.95; 95% CI, 1.96-4.45) compared with the surgical referral scenario (57.5% [115 of 200 treatment decisions] vs 67.8% [137 of 202 treatment decisions], unadjusted OR, 1.56; 95% CI, 1.04-2.34).

Secondary Outcome

Our exploratory analysis found that increasing the number of appropriate alternatives beyond 2 did not increase the odds that physicians would choose an alternative. Physicians who were randomized to receive 2, 3, and 4 alternatives in the opioid scenario had similar proportions choosing an alternative (55.2% [37 of 67], 58.8% [40 of 68], and 55.2% [37 of 67] respectively) compared with 30.5% (61 of 200) choosing the alternative in the control condition (**Table 3**).

Discussion

The aim of this study was to better understand clinical decisions to improve future health system design. Our findings challenge suggestions that physicians experience cognitive bias in medical decisions that offer multiple alternatives. Rather than causing physicians to remain with the existing

Table 2. Effects of the Number of Appropriate Alternatives on Choice of an Alternative

Variable	No./total No. of decisions (%)		Effect size, OR (95% CI)	
	1 Treatment alternative (n = 200)[a]	≥2 Treatment alternatives (n = 202)[a]	Unadjusted[b]	Adjusted[c]
Total decisions	400	404	NA	NA
Primary outcome: % choosing an alternative	176/400 (44.0)	251/404 (62.1)	2.09 (1.58-2.77)	1.90 (1.09-3.30)[d]
Scenario 1: Surgical referral with or without NSAIDs	115/200 (58.5)	137/202 (67.8)	1.56 (1.04-2.34)	NA
Scenario 2: Opioid or NSAIDs	61/200 (30.5)	114/202 (56.4)	2.95 (1.96-4.45)	NA

Abbreviations: NA, not applicable; NSAID, nonsteroidal anti-inflammatory drug; OR, odds ratio.

[a] The control group had 1 appropriate treatment alternative and the intervention group had 2 or more appropriate treatment alternatives.

[b] Estimate from a univariate logistic regression model. Does not account for within participant clustering.

[c] Adjusted for within participant clustering and includes interaction effects.

[d] *P* = .02.

Table 3. Effects of the Number of Appropriate Alternatives on Choice of an Alternative in Each Scenario Between Subgroups

Variable	No./total No. of decisions (%)			
	Control group	Intervention group		
	1 Treatment alternative (n = 200)[a]	2 Treatment alternatives (n = 67)	3 Treatment alternatives (n = 68)	4 Treatment alternatives (n = 67)
No. of decisions	400	269	68	67
Primary outcome in both scenarios: % choosing an alternative	176/400 (44.0)	174/269 (64.6)	40/68 (58.8)	37/67 (55.2)
Scenario 1: Surgical referral with or without NSAIDs	115/200 (57.5)	137/202 (67.8)	NA	NA
Scenario 2: Opioid or NSAIDs	61/200 (30.5)	37/67 (55.2)	40/68 (58.8)	37/67 (55.2)

Abbreviations: NA, not applicable; NSAID, nonsteroidal anti-inflammatory drug.

[a] The control group had the option to select 1 appropriate treatment alternative.

management plan, providing multiple alternatives substantially increased the odds that participants would shift away from an existing management plan to an appropriate alternative. Presenting 2 or more appropriate alternatives had larger effects in the scenario about opioids than in the scenario about surgery. These findings were independent of clinician preferences and robust to attention checks.

Our results are unlikely to be explained by preferences or by physicians randomly selecting an option. To control for clinician preferences, we selected alternatives with similar risk-benefit trade-offs. The specific alternatives presented to each physician were randomized from a longer list of appropriate alternatives, minimizing the influence of individual preferences on our outcome data. To reduce the risk of participants rushing through and randomly selecting options, we excluded data from those who completed the experiment too fast, or who failed attention checks. Participants who were offered multiple appropriate alternatives by design had a higher probability of selecting an alternative from their decision set. However, we found no evidence that increasing the number of appropriate alternatives offered beyond 2 increased the odds of choosing an alternative.

According to Redelmeier and Shafir,[20] introducing an additional treatment alternative increased the proportion of physicians remaining with the current care plan, rather than choosing an alternative (47% choosing an alternative in the control vs 28% choosing an alternative in the intervention; $P < .001$). Redelmeier and Shafir[20] suggested that this finding was attributable to status-quo bias, where they paradoxically remained with the existing management plan, potentially due to the increased decision difficulty when an extra treatment option was added. Chernev et al[35] described this difficulty as a response to experiencing choice overload. However, we found the opposite. Offering 2 or more alternatives significantly increased the odds that physicians would shift away from an existing management plan and choose an appropriate alternative.

This randomized clinical trial found no evidence of status-quo bias when physicians were presented with multiple choice alternatives. While our tightly controlled design allowed us to robustly test for status-quo bias, it did not permit examination of other decision-making strategies. We propose possible explanations that may inform future research. Prior evidence suggests that experts manage complexity by organizing information into meaningful subgroups or chunks.[38,39] In this trial, physicians may have mentally grouped the treatment options into clinically meaningful subgroups to simplify decision-making. Given that the risks and benefits were balanced across options, physicians may have categorized treatments into NSAIDs and non-NSAID subgroups. The value share or proportion of options belonging to a given subgroup may have influenced decision-making by increasing salience of options and potentially conveying implicit recommendations.[27] Tannenbaum and colleagues,[27] for example, found that the presentation of choice sets influenced prescribing behavior. They found when aggressive treatments were grouped together on a single line, and preferred treatments were listed individually, PCPs were less likely to choose aggressive options by 11 percentage points. Although our trial did not explicitly group options into subgroups, the number of options may have influenced how physicians cognitively organized and assessed them. These results are consistent with evidence that suggests choice behavior is adaptive and sensitive to the framing and structure of decisions.[28,30,40]

Implications for Research, Policy, and Practice

Redelmeier and Shafir[20] suggested that physicians were less likely to choose an alternative when offered 2 treatment alternatives, rather than just 1, concluding this was evidence of status-quo bias. Our findings challenge this suggestion. According to our randomized clinical trial, restricting the number of appropriate alternatives offered to physicians may lead to suboptimal decision-making. Alternatively, decision support interventions that offer multiple preferred alternatives in a choice set may encourage higher-quality care and reduce unwarranted health care variation.

Our trial highlights the need to critically reexamine early studies of cognitive bias in clinical decision-making. The introduction of electronic health systems and telehealth means physicians are exposed to more information than previous generations, further pointing to the need for updated

evidence that better reflects contemporary clinical decision-making.[41] Future trials should evaluate the effectiveness of offering 2 or more appropriate alternatives, such as in a best practice alert or suggested alternative nudge, on decision-making in a clinical setting. The effect of introducing more treatment subgroups, such as pharmacological and nonpharmacological treatments, should also be examined. To ensure interventions improve care, they should be evaluated through randomized clinical trials or randomized pilot testing, with attention given to changes in clinical care, unintended consequences, and patient outcomes.[42,43]

Strengths and Limitations

This trial has several strengths that may help explain why our results differ from those of previous studies. First, we introduced a second primary care scenario where each treatment alternative was independent and evenly matched in terms of risks and benefits. In contrast, the study by Redelmeier and Shafir[20] examined only 1 primary care scenario on osteoarthritis, and all treatment options included a referral for surgery, which could have confounded the results. Our results may differ due to the rigor of our design, an increased familiarity with best practice care for patients with hip osteoarthritis, or both.[44] Additionally, the treatment alternatives in the present trial were specific in terms of dose, frequency, and route, reducing the influence of physicians' prior experience, knowledge, or preferences. Second, our second scenario incorporated a best practice suggested alternative alert, increasing the relevance of our trial and better reflecting how clinicians are likely to be presented with multiple alternatives in real clinical practice.[16,17,45] Third, by using an online platform, we were able to recruit a more geographically diverse sample of practicing PCPs. Our physician participants were from 46 states across the US, including metropolitan, suburban, and rural locations, unlike previous studies that sampled only academic physicians in one specific state or province.[20,46] Finally, unlike the study by Redelmeier and Shafir[20], this trial was preregistered and adhered to the Template for Intervention Description and Replication (TIDieR) reporting guideline.[47,48]

Despite addressing several key limitations of prior studies, this trial has limitations. First, online studies cannot fully replicate the complexity of real clinical decision-making where guideline-concordant treatment options may be more varied and multifaceted. However, experiments in controlled conditions, including survey vignette studies, can be an effective, acceptable method for replication and identifying factors that play a role in health care variation.[34,49] This approach allowed us to isolate the effect of multiple alternatives on decision-making, minimize confounding variables and avoid harm to patients that could arise from testing the hypothesis in clinical settings.[49] Second, both of our scenarios focus on care for musculoskeletal conditions, which may limit the generalizability of our findings to other clinical areas. This is also the case for previous studies. Finally, 49 participants were excluded after randomization due to rapid completion or failed attention checks. These data integrity procedures help ensure that responses are not provided by participants who are not meaningfully engaging with the scenarios.[33] Because Qualtrics only provided data for participants who passed these checks, we were unable to determine how many physicians were originally invited or to compare characteristics of those who were included vs excluded. As with all voluntary studies, our findings may also be subject to nonresponse bias if physicians who participated differ systematically from those who did not.[50] Nevertheless, our sample is likely to be more representative than other studies that surveyed only academic physicians in a single city and required them to return responses by mail.

Conclusions

The findings of this randomized clinical trial challenge the suggestion that physicians experience cognitive bias in medical decision-making situations that offer multiple treatment alternatives. We found that offering 2 or more alternatives increased the likelihood that physicians would opt for a preferred treatment option. Interventions that offer multiple preferred alternatives may better support clinicians to deliver higher-quality care.

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Acquisition, analysis, or interpretation of data: All authors.

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SUPPLEMENT 1.
eMethods 1. Ethics Approved Study Materials
eTable 1. Scenario 1 – Surgery Referral Scenario and Randomized Treatment Alternatives Present to Control and Intervention Groups
eTable 2. Scenario 2 – Opioid Prescribing Scenario and Randomized Treatment Alternatives Presented to Control and Intervention Groups
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SUPPLEMENT 2.
Trial Protocol

SUPPLEMENT 3.
Data Sharing Statement

CHAPTER SIX: Behavioural 'nudging' interventions to reduce low-value care for low back pain in the emergency department (NUDGE-ED): protocol for a 2x2 factorial, before-after, cluster randomised trial

Chapter Six presents the protocol and theory underpinning the 2x2 factorial cluster randomised controlled evaluating the effectiveness of patient-directed and clinician-directed nudges on reducing low-value care for patients with low back pain in the emergency department (results presented in Chapter Seven)

Citation

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Behavioural 'nudging' interventions to reduce low-value care for low back pain in the emergency department (NUDG-ED): protocol for a 2×2 factorial, before-after, cluster randomised trial

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ABSTRACT

Introduction Opioids and imaging are considered low-value care for most people with low back pain. Yet around one in three people presenting to the emergency department (ED) will receive imaging, and two in three will receive an opioid. NUDG-ED aims to determine the effectiveness of two different behavioural 'nudge' interventions on low-value care for ED patients with low back pain.

Methods and analysis NUDG-ED is a 2×2 factorial, open-label, before-after, cluster randomised controlled trial. The trial includes 8 ED sites in Sydney, Australia. Participants will be ED clinicians who manage back pain, and patients who are 18 years or over presenting to ED with musculoskeletal back pain. EDs will be randomly assigned to receive (i) patient nudges, (ii) clinician nudges, (iii) both interventions or (iv) no nudge control. The primary outcome will be the proportion of encounters in ED for musculoskeletal back pain where a person received a non-indicated lumbar imaging test, an opioid at discharge or both. We will require 2416 encounters over a 9-month study period (3-month before period and 6-month after period) to detect an absolute difference of 10% in use of low-value care due to either nudge, with 80% power, alpha set at 0.05 and assuming an intra-class correlation coefficient of 0.10, and an intraperiod correlation of 0.09. Patient-reported outcome measures will be collected in a subsample of patients (n≥456) 1 week after their initial ED visit. To estimate effects, we will use a multilevel regression model, with a random effect for cluster and patient, a fixed effect indicating the group assignment of each cluster and a fixed effect of time.

Ethics and dissemination This study has ethical approval from Southwestern Sydney Local Health District Human Research Ethics Committee (2023/ETH00472). We will disseminate the results of this trial via media, presenting at conferences and scientific publications.

Trial registration number ACTRN12623001000695.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ First randomised controlled trial to test the impact of clinician-directed and patient-directed behavioural nudges on reducing low-value care for back pain in the emergency department.
⇒ Tests scalable interventions to align care with clinical guidelines.
⇒ Study design informed by pilot studies, hospital administrative data, clinician focus groups, patient involvement and behavioural economic theory.
⇒ Intervention period of 6 months may not capture potential seasonal variations in care.
⇒ Clinicians will not be blinded to the nudge interventions.
⇒ Including a 'before-after' component in the trial will allow us to investigate potential Hawthorne effects.

BACKGROUND AND RATIONALE

The problem

There is increasing global recognition that use of low-value care—healthcare services that are ineffective or offer little patient benefit—is a pervasive problem.[1] An Australian systematic review identified 156 low-value health services listed on the Medical Benefits Schedule, that were either ineffective or unsafe.[2] Examples included routine diagnostic imaging for low back pain, opioid overuse for non-cancer pain and several types of spinal surgery.[2] In recognition of the impact on quality and safety of care and resource stewardship, reducing low-value care has become an international priority, motivating awareness campaigns across 25 countries.[3]

Low back pain is the leading cause of disability worldwide,[4] is the fifth most common reason to visit the ED[5] and is often associated with low-value care.[6] Our recent analysis of hospital administrative data on 6393 back pain presentations to the ED found 23.6% received lumbar imaging and 69.6% received opioids.[7] Neither of these services is recommended for management of uncomplicated low back pain because of their poor benefit-to-harm profile. Most low back pain is benign in nature and imaging adds little information to the clinical assessment.[8] Non-indicated lumbar imaging can have immediate harms, such as exposure to radiation, increased patient anxiety, increased wait times (which can increase morbidity, decrease patient satisfaction and contribute to ED overcrowding)[9] and increased length of stay.[10] Potential long-term harms of imaging include the detection of irrelevant findings (eg, 'degenerative discs') that correlate poorly with symptoms, and trigger ineffective or unnecessary procedures such as spinal surgery.[11]

Similarly, harms from opioids are well documented. In the short-term opioids can cause nausea, vomiting, constipation and dizziness.[12] Potential long-term harms include dependence, overdose and death.[12] Between 2007 and 2016, the number of Australians dying or hospitalised from poisoning by prescription opioids increased by 38% and 62%, respectively.[12] Evidence from a recent high-quality trial found that for people with acute low back pain, an opioid analgesic strategy provided no significant difference in pain severity compared with placebo.[13–15] Overuse of low-value care such as opioids at discharge is often coupled with underuse of high-value care options such as advice, non-drug care and simple analgesics.[16]

Past interventions

There is limited evidence on the effectiveness of strategies to reduce use of low-value imaging and opioids for low back pain. A 2015 systematic review and earlier Cochrane review concluded there was an absence of effective strategies to reduce low-value imaging.[17 18] Similarly, a 2020 systematic review of opioid stewardship interventions showed that although several strategies have been implemented (eg, education, hospital policies, electronic medical record (eMR) changes, registries), there was a lack of high-quality randomised controlled trials (RCTs) to determine whether these strategies work.[19] Recently, an intervention to reduce low-value care for low back pain was tested in a high-quality RCT in 4491 patients attending the ED.[20] The intervention, which focused on resource-intensive clinician education, provision of heat packs and department-level audit and feedback, reduced opioid initiation, but it did not change imaging rates. Tsega *et al* found adding cues to eMR request forms could reduce use of lumbar X-rays in ED, but use of advanced imaging was unchanged or increased.[21] The success of behaviour change interventions to reduce low-value care has therefore been mixed, and the evidence for reliable strategies to implement in healthcare settings is uncertain. Key factors yet to be addressed in these interventions are the beliefs and biases that can drive decision making.[22]

Insights from behavioural economics

Research from the field of behavioural economics suggests that decision making, including clinical decision making, can be influenced by context, heuristics and cognitive biases.[23 24] For example, Prospect Theory proposes that despite clinicians being highly skilled and

Table 1 Relevant heuristics and biases

Heuristic or bias	Description
Ambiguity aversion	*Ambiguity aversion* describes when the decision maker will pursue testing to increase certainty, even if not recommended, or avoid making decisions with ambiguity.[23 56] For example, clinicians with a low tolerance to ambiguity may order unnecessary imaging tests for patients with uncomplicated back pain to increase clinical information before making a diagnosis.[57]
Commission bias	*Commission bias* describes when clinicians prefer to provide something (eg, a test or treatment), rather than nothing, even when nothing is the clinically appropriate decision.[26 58] For example, a cross-sectional survey study emergency physicians found that 97% reported that they had personally ordered some unnecessary imaging.[59] In addition, a survey of Australian hospital pharmacists (n=135) found that even when patients have not needed opioid analgesics in the past 48 hours before discharge, over 70% provided a take home opioid 'just-in-case'.
Default or status quo bias	*Default or status quo bias* describes when the structure or complexity of a decision leaves clinicians opting to maintain the existing course of action, even when it is an inferior choice.[27] For example, reducing the default quantity populated in the eMR for opioids can modestly reduce the number of opioids prescribed.[60]
Framing effect	*Framing effect* describes when decision makers' preferences and judgements are influenced by how information is described or framed.[27] For example, two hospital field experiments to increase handwashing found that framing hand hygiene in terms of benefits to the health of the patients was more effective than framing in hand hygiene in terms of benefits to the health of the doctors.[44]
Present bias	*Present bias* describes when people value immediate benefits or harms, over the long-term consequences of their decisions.[61–64] For example, a clinician may request imaging and/or opioids because they overweight the immediate benefits (such as increased patient satisfaction and reduced pain scores) over the potential long-term harms (such as overdiagnosis and opioid dependence).[22 65]

eMR, electronic medical record.

knowledgeable professionals, they are still susceptible to cognitive biases.[25] There are many examples of humans relying on heuristics, or rules of thumb, to make decisions.[25] In some contexts, these heuristics can lead to biases, systematic errors or suboptimal decision making. A systematic review of 213 studies identified 19 types of heuristics and biases that were present in patients' and clinicians' medical decision making.[26] Seventy-three studies looked at decision making in clinicians, with 80% (n=51) of these finding a heuristic or bias present in clinical decision making.[26] Similarly, 140 studies looked at patients, with 61% (n=86) of studies finding a heuristic or bias present in healthcare decisions.

Therefore, it is important to understand the heuristics and biases that may affect decision making in the ED when designing interventions to reduce low-value care. The heuristics and biases presented in table 1 have been researched in clinical decision making and are particularly relevant to imaging and opioid prescribing at discharge. These heuristics and biases could help explain the persistence of low-value care despite clinician education and awareness campaigns but may also offer possible solutions.

The use of nudges

'Nudges' can leverage heuristics and biases to improve decision making to increase guideline concordant care. Nudges are changes to the way choices are presented or structured that can alter decision making without restricting or prohibiting options.[27] Nudges are a light-touch, low-cost and scalable way to align care with clinical guidelines.[28 29] A systematic review that included 28 RCTs found that computer reminders delivered to clinicians during their routine activities improved protocol adherence by a median of 4.2%, with some trials reporting larger effects. In addition, a recent systematic review that included 42 RCTs examining the use of nudges such as social norms, defaults and reminders found that 86% of them were effective at improving guideline concordance.[29] Several of these techniques could be implemented in ED settings to align care with clinical guidelines.

Identifying the most relevant nudge strategies and understanding their implementation in a broader healthcare context is essential.[30] Jesse and Jannach[31] proposed a taxonomy of nudging mechanisms that included decision information, decision assistance, decision structure and social decision appeal.[31] Decision information supports decision makers by simplifying complex information and highlighting decision consequences.[28] Decision assistance brings forward information that clinicians are likely aware of but may forget to consider in each clinical judgement.[29] Changing the decision structure can involve increasing the effort and friction for guideline discordant decisions and reducing it for guideline concordant decisions. It can also include suggesting guideline concordant alternatives or substitutes. Social decision appeal leverages the power of messenger effects and social norms. These nudging mechanisms should be considered in the broader decision-making context when designing nudge interventions.

Given both clinicians and patients can be influenced by decision-making biases, there is an important role for both patients and clinicians to be involved in improving healthcare decisions. However, there is little evidence about to what nudge strategies are effective at reducing low-value care in the ED. In addition, it is not known if directing nudges towards patients, clinicians or both is most effective. To our knowledge, this will be the first RCT to test the impact of scalable clinician-directed and patient-directed behavioural nudges on reducing low-value care for back pain in the emergency department (ED).

STUDY AIMS

Primary aim

To determine, for people with back pain due to a musculoskeletal condition presenting to ED, the effectiveness of patient nudges, clinician nudges or both interventions compared with no nudge intervention on reducing encounters involving low-value care (non-indicated lumbar imaging test, opioid at discharge or both).

Secondary aims

The secondary objectives of this study are:

- To determine if the interventions lead to non-inferior short-term patient-reported outcomes (satisfaction with care, worry, pain, function, quality of life) compared with a no nudge control group.
- To calculate the cost-effectiveness of the interventions compared with a no nudge control group.
- To evaluate unintended consequences (representation rate, readmission rate).
- To explore patient and clinician experiences of the interventions.

METHODS AND ANALYSIS

Study design

NUDG-ED is a 2×2 factorial, open-label, before-after, cluster RCT design (figure 1). This involves randomising eight hospital EDs to one of four groups after a 3-month period where all sites are in a no nudge control group. We will require 2416 encounters for back pain due to a musculoskeletal condition across 8 sites over a 9-month study period (3-month before period and 6-month after period). NUDG-ED is planned to commence in April 2024, ending in December 2024.

We used the Standard Protocol Items: Recommendations for Interventional Trials checklist to report the protocol.[32]

Study setting

The participating hospitals are located across three Local Health Districts (LHDs) in Sydney (Western Sydney LHD, Nepean Blue Mountains LHD, Southwestern Sydney LHD). These are public hospitals in culturally

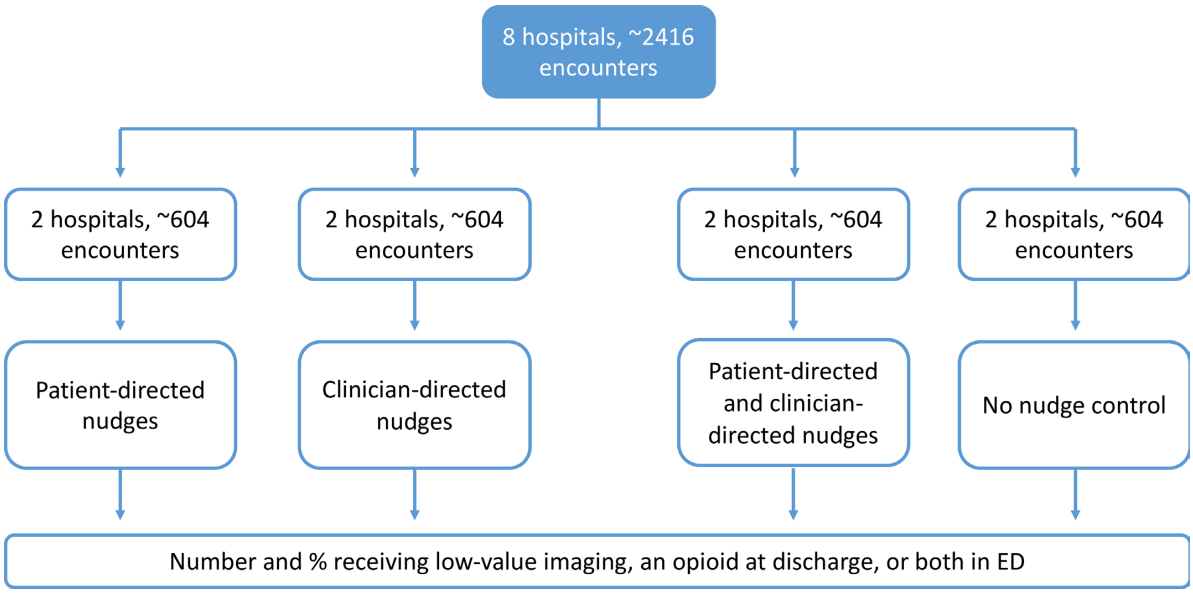

Figure 1 2×2 factorial, open-label, before-after, cluster randomised controlled trial design.

and linguistically diverse, metropolitan areas that provide emergency care for general medical conditions. Between 20% and 50% of residents across these LHDs were born overseas and approximately 50% speak a language other than English at home. The regions of Western and South-western Sydney have higher than average levels of socio-economic disadvantage compared with the state of New South Wales.[33] Most EDs in Australia are publicly funded and have no out-of-pocket expenses for Australian citizens and most permanent residents to attend.

Site recruitment

We adopted a pragmatic approach to site selection. We recruited sites based on the capacity of the sites to make eMR changes. To participate in the trial, sites were required to have an eMR system that could identify patient participants based on their presenting problem and provide a specific eMR pop-up alert when a clinician orders imaging or opioids for these patients.

Randomisation and group allocation

We will use cluster randomisation because the intervention will be at the hospital level. We will randomly allocate the eight hospitals (clusters), into one of four groups: (i) patient nudges; (ii) clinician nudges; (iii) patient nudges and clinician nudges, (iv) no nudge control. To create the randomisation list, a trial statistician will use computer-generated random numbers.

Participants and recruitment

Clinician participants

Clinician participants will be ED clinicians at study sites who are involved in the care of patients presenting to the ED with a primary complaint of low back pain. This includes physicians (Junior Medical Officer, Registrar, Consultant, Career Medical Officers), nurses and physiotherapists. After the intervention period, ED Directors will invite all ED clinicians to complete a survey and a subset to participate in semi-structured interviews. We will be using a purposive sampling approach for clinician interviews to ensure a diverse range of clinician experience, age, gender and interest in the management of back pain. We do not have capacity to collect data on individual clinician characteristics because these details are not recorded in the current eMR system.

Patient participants

For the health service measures, including our primary outcome, patient participants will be adults aged 18 years or over who present to the ED during the study period with back pain due to a musculoskeletal condition. We will invite a sub-sample of patients who present to ED with low back pain during the study, to participate in a follow-up period via text message survey. To confirm eligibility, clinician investigators will use the eMR to identify people diagnosed with back pain due to a musculoskeletal condition using a list of codes from Systematised Nomenclature of Medicine Clinical Terms Australia (SNOMED-CT AU) (online supplemental table 1). Information about the study and how to opt out will be displayed on the 55-inch advertising screen located in the waiting room. Patient participants will not be invited to complete the survey if they were diagnosed with a non-musculoskeletal condition e.g. renal colic, if they did not have a valid mobile phone number on record, if they required a translator, or if they opted out of the patient survey in the ED waiting room.

Patient and public involvement

Patient nudges have been co-designed with patients, public and clinicians. Two consumer advisors have

been appointed to support throughout key stages of the research including reviewing the protocol and patient-reported outcome measures, analysing patient survey feedback and interpreting results.

Sample size

A previous study of patients presenting to ED with low back pain suggests 31.7% (95% CI 22.9 to 41.6)[34] received opioid prescription at discharge and 30.3% (95% CI 23.7 to 38.0) received non-indicated lumbar imaging.[35] To detect an effect of the patient nudges or clinician nudges on the number and proportion of encounters involving low-value care, with an absolute difference of 10% (eg, event rate 30% in the control hospitals vs event rate 20% in intervention hospitals) and with 80% power, alpha set at 0.05, assuming an intraclass correlation coefficient (ICC) of 0.10 and an intraperiod correlation (IPC) of 0.09 (ie, between the before and after periods, within each site) and accounting for variable cluster sizes, we would require 2416 encounters for back pain due to a musculoskeletal condition across 8 sites, over a 9-month trial period (ie, ~302 encounters per site, over 3-month baseline and 6-month intervention period). Our sample is based on an achievable and conservative estimate that IPC is less than ICC and assumes no loss to follow-up. Losses to follow-up are very unlikely because our primary outcome is based on routinely collected health service data.

For patient-reported outcomes, we calculated power based on the mean of five items related to 'Overall Assessment of ED Experience' of the Press Ganey Survey (range 1–5), at 1-week follow-up. We chose this measure because patient experience is a key priority for hospitals in Australia and have powered the study to detect a meaningful drop in patient experience due to either intervention. We assumed a mean of 4.2 points, an SD of 1.9,[36] a non-inferiority margin of 0.5 point (ie, 0.5 units is the maximum acceptable drop in patient experience), an IPC and ICC of 0.01, the minimum required sample size for 80% power was 57 patients per site, over the 6-month intervention period (456 patients in total). The expected response rate of the survey is around 30-50%.[20]

Blinding

It is not possible to blind patient participants to the nudge interventions, although measures will be taken to reduce performance bias, for example, masking patients to the study hypothesis. At least one member of the research team and a blinded statistician will be unaware of site allocation. Outcome assessors and trial staff reviewing clinical notes will also be blind to site allocation. Clinicians at all sites will receive an email from their ED director endorsing the trial and explaining their group allocation at the start of the trial. To investigate potential Hawthorne effects, we will compare use of low-value care in the no nudge control sites before and after the email from the ED director notifying staff of the trial (see 'Intervention delivery' section). Statistical analysis and interpretation will also be performed blind to group allocation. Unblinding of the statistician and independent trial staff will occur once data analysis and interpretation are complete.

INTERVENTIONS

Patient nudges: making decision information salient

Patient nudges will include six digital decision information posters displayed on 55-inch LCD screens (patient nudge A—figure 2) and a decision information brochure (patient nudge B—figure 3) based on behavioural

Figure 2 Patient nudge A—example of a decision information poster targeting opioids and imaging for back pain. These digital posters will be displayed on LCD screens, these will also include QR codes linking to patient nudge B, the decision information brochure.

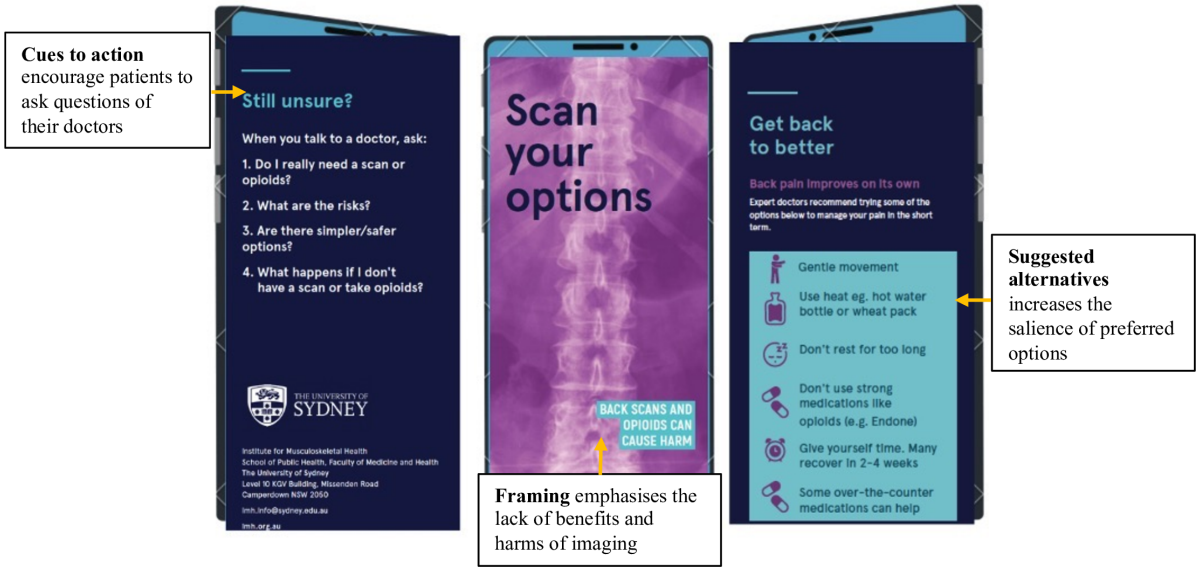

Figure 3 Patient nudge B—example of smartphone-based decision information brochure. Patients will have access to this information via a QR code or printed decision information brochures.

economics theory (see 'Theory and evidence behind the patient nudges' section). Patients can access patient nudge B using their smartphone (via the QR code on the digital posters) or a paper version that will be stocked in a brochure holder attached to the LCD screen. 'Scan here for more information' is on each poster to direct patients to the patient information brochure. A full list of intervention materials included is shown in online supplemental figure 1.

All decision information posters will be translated into Arabic, simple Chinese and Vietnamese. Up to two non-English language posters will be included in rotation in each of the sites based on the relevant LHD data on languages most spoken.

Theory and evidence behind the patient nudges

These patient information materials were originally designed by an ad agency and further refined by investigators using pilot studies and behavioural economic theory.[37] The interventions use several behavioural science techniques that can be grouped under broad categories in the nudge taxonomy by Jesse and Jannach.[31] The patient nudges are *making decision information visible* for patients in the ED waiting room. They provide simplified information that is directly relevant to immediate next steps for patients with low back pain. The *salience* of this information is increased by presenting the relevant messages on attractive, attention-grabbing posters that are presented on a large, prominently placed LCD screens in the ED waiting room.[28] The patient nudges will *frame* the decision consequences in terms of the lack of benefits and the immediate potential harms of imaging and opioids, rather than long-term harms (online supplemental figure 1).

Social norms and messenger effects can influence how people receive information.[38 39] A systematic review of nudges to improve clinical decision making found that in 16 of the 17 RCTs that used social norm and messenger effect resulted in improved clinical decision making.[29] This could be due to the authority, trustworthiness, relatability or perceived knowledge of the messenger. However, there are contexts in which the messenger has no effect.[40] In addition, a meta-analysis that examined 297 studies found that the use of descriptive norms (describing what most other people do) can be effective at directly influencing behaviour.[41] Attempting to leverage these potential messenger effects, two of the six decision information posters will include the image of two physicians (one male, one female) to convey credibility and trustworthiness of the information. In addition, two posters will leverage descriptive social norms. One poster that says 'most people' will experience as much pain relief from anti-inflammatories, as they do from opioids, with fewer side effects, and the other poster states that back scans are not helpful for 'most people' with low back pain.

Suggested alternatives involve increasing the salience of more preferable options that users can substitute the targeted behaviour with.[31] We have suggested that instead of using opioids patients can use evidence-based management techniques including gentle movement, using heat, over-the-counter medication and giving time for recovery. These nudges aim to provide patients with information to help them to better understand the costs and benefits or imaging and opioids.[37] Our randomised proof-of-concept study found that, compared with standard care, these patient nudges reduced intention to request imaging by 1 point on a 10-point scale (95% CI −1.6 to −0.4).[42]

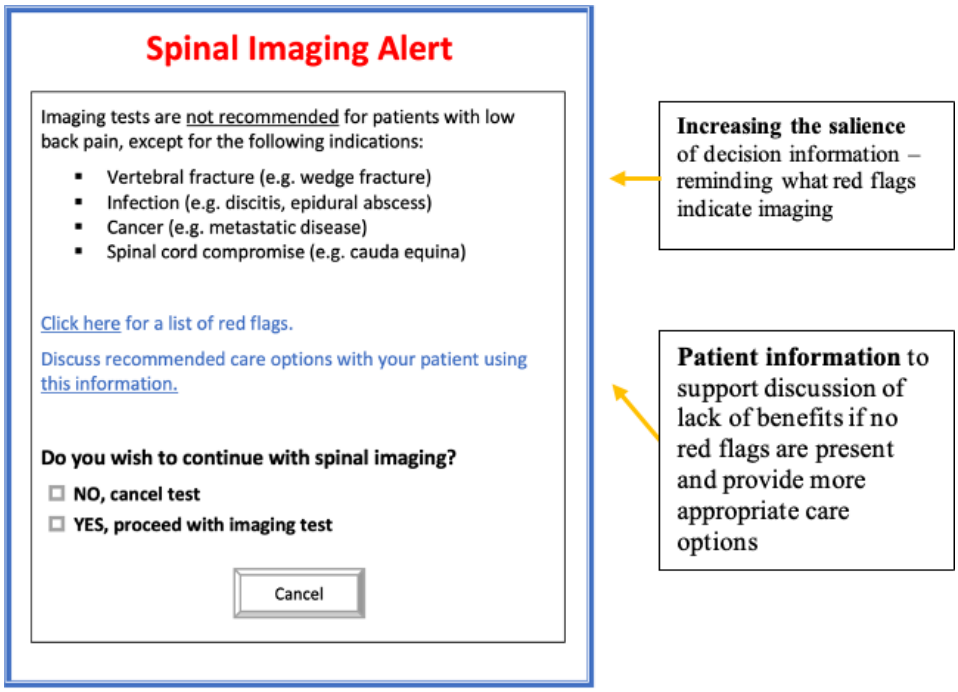

Figure 4 Clinician nudge A—computer alert when clinicians try to order imaging for low back pain. The pop-up reminds clinicians imaging is not recommended and includes a clickable link to the decision information brochure.

The c*ues to action* used in the patient nudge intervention aim to encourage patients to start a conversation about their care options with their ED clinician.[37] Information is provided at a time just before making care decisions with their clinician. Given its relevance and timing to patients with back pain, the information should be readily available in their memory and can be used to inform shared decision-making discussions with their clinician.

Clinician nudges: computer alerts

The clinician nudges were informed by a pilot study we conducted with primary care physicians.[43] The interventions include three small changes to the current computerised order systems that are triggered only for patients who are flagged in the workflow as presenting with low back pain.

Clinician nudge A (figure 4) is a behaviourally informed computer alert (see 'Theory and evidence behind the clinician nudges' section) that appears when a clinician attempts to order imaging test for patients recorded as presenting with back pain. This interrupts habitual ordering and provides decision assistance by reminding clinicians that imaging is not recommended without features of serious pathology and providing them clear guidance on what pathologies would warrant imaging. The prompt will also provide them the key information from the patient decision information brochure to support a conversation with the patient about preferred care for low back pain (see online supplemental figure 1). If the clinician does suspect serious pathology or wish to continue, they will be able to do so as normal. If they decide imaging is not necessary, they will be able to cancel the order.

Clinician nudge B (figure 5) is also a behaviourally informed computer alert that appears when a clinician attempts to administer an opioid medicine for a person with back pain. Before proceeding with the administration, the alert reminds clinicians that opioids are not recommended for back pain and provides a list of suggested non-steroidal anti-inflammatory drugs (NSAIDs) to choose from instead.[13] The nudge for ordering an opioid while a patient is in the ED will be muted for every second order to reduce alert fatigue. Clinicians who attempt to order or prescribe opioids for a person diagnosed with uncomplicated back pain will receive an alert reminding them that take-home opioids are not recommended. It also provides evidence-based advice for the patients at home care (figure 5).

No nudges will restrict clinicians testing or treatment options; it is still within their scope to provide imaging or opioids if they deem it suitable. The nudges disrupt habitual ordering and provide decision information. Our outcome relies on routine recording practices of clinicians at participating hospitals and could be affected by differences in recording across the eight sites. We do not have capacity to collect data regarding other interventions patients received while in ED (eg, education or manual therapy) because these data are not provided in coded format for extraction from the eMR.

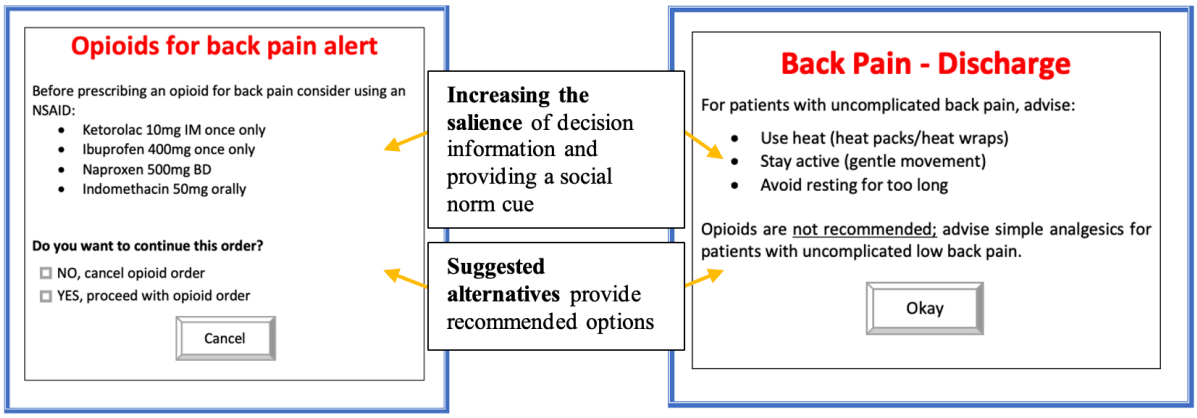

Figure 5 Clinician nudge B—computerised alert when clinicians try to administer an opioid medication for back pain. The pop-up reminds clinicians opioids are not recommended and provides suggested alternatives for more appropriate care. BD, two times a day; IM, intramuscular; IV, intravenous; NSAID, non-steroidal anti-inflammatory drug; PO, orally.

Theory and evidence behind the clinician nudges

The clinician nudges change the decision structure and provide assistance to clinicians at the time of decision making.[28] They take the form of active choice alerts that disrupt the habitual flow of test and/or opioid ordering, increase the option-related effort and provide just-in-time information to support decision making. Both nudges remind clinicians that opioids and imaging may not be appropriate for musculoskeletal back pain.[44] The opioid alert provides clinicians *suggested alternatives* to remind clinicians that safer care alternatives are available for them to provide which may alleviate *commission bias* effects (figure 5).[31 45] The lumbar imaging alert reminds the clinician of the red flags that would indicate imaging is required and provides them information on the lack of benefits and safer care options and a cue to discuss it with the patient. It also provides a shared decision-making prompt and supporting information that can be discussed with patients on when imaging may be helpful, when it is not and what the evidence says works for treating uncomplicated back pain. Clinicians may override the alerts and continue to order imaging or opioids if clinically indicated.

No nudge control

The no nudge control group will receive an email communication from the ED Director at the start of the NUDG-ED intervention period notifying them of the trial. No nudge interventions will be delivered to these hospitals. Waiting room screens will display standard hospital messaging, without any content on back pain.

Intervention delivery

ED clinician participants in the intervention and control groups will be officially notified by their ED Director of the start date and aims of the trial, and to give explicit support for the trial. Nudges that aim to support improved clinical decision making may be more widely accepted and reduce backfire effects if there is transparency about the purpose and intent of the nudges.[46] A study by Loewenstein *et al*[46] found that explicitly disclosing a nudge did not meaningfully affect the impact of the nudge. Clinicians may also value the nudges more knowing that ED Directors have been involved in co-designing the intervention materials to ensure they are suitable for their ED context.[37]

An LCD advertising screen (55-inch) will be newly installed in the ED waiting room of each participating hospital. In hospitals randomised to receive the patient nudge intervention, the screen will begin displaying the decision information posters in the form of a slideshow on loop (~10 s per poster). At hospitals not allocated to the patient nudge intervention group, the screens will display standard hospital messaging. Investigators can launch and monitor the fidelity of the patient nudges remotely via web analytics and LCD advertising screen content management system. Hospitals randomised to the clinician nudges will launch the computer alerts in the ED eMR. Interventions will run for 6 months at each intervention site.

OUTCOME MEASURES

Primary outcome

The primary outcome will be use of low-value care, defined as the proportion of encounters for back pain due to a musculoskeletal condition where a person received a non-indicated lumbar imaging test, an opioid at discharge or both, in the ED over a 9-month period. We chose this composite outcome because it is a meaningful metric to ED clinicians. Clinician researchers will perform chart reviews every month for all participants who present with low back pain and receive imaging to understand and code if it was *non-indicated* imaging (ie, imaging provided in the absence of clinical features of serious pathology) using reliable methods we have published.[35] Opioids provided or prescribed at discharge

for patients diagnosed with 'non-serious' low back pain (ie, low back pain with non-specific cause or low back pain with neurological signs and symptoms—see online supplemental table 1) will be coded as low value.

For patient participants who received imaging, the following sections of the clinical chart will be examined, and used to code the primary outcome (online supplemental figure 2):

- Order comment
- Clinical or case notes
- Reason for imaging request
- ED discharge letter
- ED imaging report
- Hospital admission report

A clinician researcher will screen the clinical charts of participants who received lumbar imaging and identify if there were documented clinical indications. To do this, a checklist of guideline-endorsed imaging indications will be completed by the reviewing clinician via a standardised chart review in Research Electronic Data Capture (REDCap). Approved chart reviewers (clinician researchers) will receive a list of participants in the trial whose charts require review. Indications for imaging will be based on international clinical guidelines[8] and our previous work on coding the appropriateness of imaging for low back pain in ED (online supplemental figure 2).[35]

If patients are diagnosed with 'non-serious' musculoskeletal low back pain (i.e., they have a SNOMED-CT AU code corresponding with either category (1) low back pain with non-specific cause or category (2) low back pain with neurological signs and symptoms; see online supplemental table 1) and they receive opioids at discharge, this will be coded as low-value care. This decision was informed by advice from the ED clinicians in our team.

A 6-month intervention period could be a limitation of the study design as we will not capture potential seasonal variations in ED care. A time series analysis of Western Australia metropolitan EDs showed variation in the number and case mix of patient presentations over the course of the year, with peaks in winter.[47]

Secondary outcomes

Patient-reported outcomes

A number of patient-reported outcome measures will be collected from a minimum of 456 patients up to 1 week after their index ED visit in the 3-month before period and 6-month after period. These measures include:

- *Patient experience:* two items related to 'Overall Assessment of ED Experience' and two items from 'Medical Provider' from 36-item Press Ganey ED Survey.[48]
- *Pain intensity:* Numeric Pain Rating Scale,[49] the pain duration question from Orebro Musculoskeletal Pain Questionnaire[50] and disability measured using the 2008 adaptation of item 8 of the 36-Item Short Form Health Survey by Henschke *et al*.[51]
- *Health-related quality of life:* EQ-5D-5L health-related quality of life indicators.[52]
- *Reassurance:* generic reassurance subscale from Consultation-based Reassurance Questionnaire.[53]
- *Patient participation in decision making:* CollaboRATE Tool.[54]
- *Referrals to specialist.*
- *Intention to seek second opinion*: one item from the National Patient Safety Foundation established by the American Medical Association.[55]
- *Patient beliefs about imaging and opioids:* items 13 and 14 from the survey by Jenkins *et al*[17] and a new statement on patient beliefs on the effectiveness of opioids.

See online supplemental file 1 for full list of patient-reported outcome measures.

Process measures

We will be evaluating patient beliefs, patient reassurance and perceived helpfulness of the computer alerts as potential mediators of the intervention effect.

Service outcomes

- Proportion of patients admitted to hospital (excludes patients sent to the ED short stay units).
- Proportion of patients who receive advanced lumbar imaging tests (CT/MRI=yes, X-ray/no imaging=no).
- Time in the ED (triage time to the ED discharge or admission time, including the time in short stay units).
- Hospital costs (including intervention costs, ie, LCD screens, installation costs, staff time, IT support costs), cost-effectiveness.
- Use of opioids in the ED (eMeds).

Fidelity measures

- Clinicians' awareness and opinion of interventions. See online supplemental file 2 for full list of clinician survey questions.
- Patient engagement (use of QR code on ED waiting room screen).

Unintended consequences

- Proportion of patients representing with low back pain to the index ED within 48 hours (this aligns with hospital performance indicators and is readily captured in hospital administrative data).
- Proportion of patients with unintended 30-day representation.
- Proportion of patients who are readmitted.
- Proportion of patients who left the ED without treatment.
- Proportion of patients diagnosed with non-musculoskeletal pain who were administered an opioid.

Experiences with interventions

Semi-structured interviews (15 min via Zoom) with patients and clinician participants at each site to discuss implementation (usage, reactions to and awareness of interventions) (n=~40); we will attempt to capture clinician beliefs about the usefulness and impact of the

interventions. We are particularly interested if the nudges and information helped patients and clinicians in their decision making. We are asking clinicians if they noticed the alerts and if they found them appropriate and useful. We are also asking if clinicians had patients refuse imaging or opioids when they were offered.

DATA COLLECTION METHODS

Data collection

We will use Discern Analytics to build a standardised query to extract the routinely collected health service delivery data at participating sites from Cerner software. In the 3-month control period and during the intervention period, the same health service delivery measures will be extracted from all sites, every week, until the end of the trial at 6 months of follow-up. This collection system has worked well in our previous trial[20] and avoids additional workloads for ED staff. We will collect patient-reported outcomes from a random subsample of patients who presented during the 9-month trial period (n=456 or ~12% of sample). We will use automated text messaging to contact patients 1 week after the index ED visit. Participants will be referred to a brief self-reported online questionnaire.

Health-service data

Using electronic clinical charts, a data manager at each of the participating LHDs will extract re-identifiable data on people presenting with back pain (see online supplemental figure 2 for specific items), to a REDCap database. REDCap is suitable for 'highly protected' data—data are stored securely, is encrypted in transit and at rest. Only approved study investigators will have access to identifiable data using a personal REDCap login and password. We will de-identify data for analysis and store the de-identified dataset in the University of Sydney's Research Data Store.

Clinical notes and coding of appropriateness

Clinical notes will be accessed by approved NUDG-ED investigators using remote access to the eMR. For all other participants, only the discharge summary will be extracted from the eMR to the main study datasheet. Clinician investigators who review the appropriateness of imaging will use a standardised survey in REDCap to extract data and score appropriateness. This process is informed by our previous work.[35] We anticipate we will require 10–20 clinicians to assist with case note reviews.

Patient-reported data

We will collect patient-reported data via a secure web application, REDCap. We will send participants a text message invitation via Twilio to participate and a REDCap link to complete an online survey.

STATISTICAL METHODS

Data analysis will be blinded, by intention-to-treat and guided by a published statistical analysis plan. Analysis will be conducted by an independent biostatistician and checked for accuracy.

- Primary analysis: to evaluate the effect of the intervention on the proportion of encounters for back pain due to a musculoskeletal condition where low-value care was provided, we will use a multilevel regression model, with a random effect for cluster and patient (assuming some patients may have several encounters during the study period), a fixed effect indicating the group assignment of each cluster and a fixed effect of time.
- Secondary analysis: dichotomous outcomes will be compared between groups using generalised estimating equations (GEE) considering clustering effects. Continuous secondary outcomes will be analysed using the same GEE model with appropriate link function.
- Cost-effectiveness analysis: cost-effectiveness analysis of the NUDG-ED interventions compared with current emergency care will be done from the health system perspective. For this, we will measure all costs related to the delivery of the intervention (ie, LCD screens, installation costs, staff time, printed resources, IT support). We will also calculate the costs of imaging and opioid use in control and intervention groups. We will present the incremental cost-effectiveness ratio as the incremental cost per patient avoiding low-value care. We will also estimate the incremental cost per quality-adjusted life year gained, using utility weights from the EQ-5D-5L.
- Qualitative analysis: we will conduct a framework analysis to explore experiences with the nudge interventions.

AUDITING

We have not planned a formal audit. However, we will arrange independent auditing of the trial process and documents if needed. This trial is registered with ANZCTR (ACTRN12623001000695) and subject to the usual audits for clinical trials in Australia.

Data monitoring committee

This study does not require a data monitoring committee because it does not focus on life-threatening diseases, vulnerable populations or potentially harmful experimental interventions.

ETHICS AND DISSEMINATION

This study has ethical approval from Southwestern Sydney LHD Human Research Ethics Committee (2023/ETH00472). The trial received a waiver of informed consent because: (a) it is impractical to consent all the clinicians and patients and the project could not practicably be done if informed consent were required; (b) as a behavioural intervention, the requirement for patients or clinicians to consent to participation would invalidate the scientific validity of the experiment or (c) both.

Participant information and consent forms are included in the online supplemental files 3 and 4. Any important protocol modifications will be reported to investigators, research ethics committee/institutional review boards, trial registries, journals and trial regulators. All authors will be required to meet the International Committee of Medical Journal Editors criteria. We will disseminate the results of this trial via media and presenting at conferences and publications in scientific journals.

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Competing interests None declared.

Patient and public involvement Patients were involved in the design of this research. Refer to the 'Methods' section for further details.

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CHAPTER Seven: Behavioural nudges to reduce low-value care for low back pain in the emergency department (NUDG-ED): A 2x2 factorial, pragmatic cluster randomized trial

Chapter Seven presents the results for the first randomised controlled trial to evaluate patient-directed and clinician-directed nudges on reducing low-value care for patients with low back pain in the emergency department.

Citation

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Research

Behavioural nudges to reduce low-value care for low back pain in the emergency department (NUDG-ED): a 2 × 2 factorial, pragmatic cluster randomized trial

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Abstract

Background: Low-value care exposes patients to unnecessary risk and wastes scarce health resources. We aimed to determine if patient- or clinician-directed nudges could reduce low-value care for low back pain in the emergency department.

Methods: We conducted a 2×2 factorial, cluster randomized controlled trial involving patients with low back pain presenting to emergency departments. Eight emergency departments were randomized to receive patient nudges (6 electronic information posters discouraging unnecessary imaging and opioids, displayed on 55-inch screens in waiting rooms), clinician nudges (3 electronic health record alerts that provided indications for lumbar spine imaging and suggested alternatives to opioids), both patient and clinician nudges, or no nudges. The primary outcome was the proportion of encounters for low back pain with low-value care, defined as non-indicated lumbar spine imaging test, opioid prescription at discharge, or both. We calculated odds ratios (ORs), adjusted for baseline and clustering.

Results: There were 3770 encounters for low back pain during the study period. The overall baseline prevalence of low-value care was 41.6%. During the intervention period, the proportion of encounters with low-value care reduced to 36.4% with patient nudges versus 38.1% without, but the difference was not significant (adjusted OR 0.80, 95% confidence interval [CI] 0.51 to 1.27). The proportion of encounters with low-value care was 39.4% with clinician nudges versus 35.0% without (adjusted OR 1.31, 95% CI 0.84 to 2.05). We did not observe an interaction effect between the interventions ($p = 0.4$). The patient nudge may have reduced strong beliefs among patients in the value of imaging for low back pain. We found no important differences in secondary outcomes.

Interpretation: Nudges — including waiting room information posters targeting patients and electronic health record alerts targeting clinicians — did not reduce low-value care in emergency departments. **Trial registration:** www.anzctr.org.au, ACTRN12623001000695

Low-value care places patients at risk, wastes considerable resources, and diverts them from effective care.[1] Low back pain is a leading reason why patients present to emergency departments worldwide[2] and is frequently associated with low-value care. In the United States, emergency department presentations for low back pain tripled between 2016 and 2023 (from 807 636 to 2 342 818).[3] In emergency departments, nonindicated imaging and opioid prescribing at discharge are considered low-value care for patients with low back pain.[4] Imaging overuse unnecessarily exposes patients to harm from radiation, anxiety, and incidental findings leading to further low-value care.[5] Overuse of opioids also has well-documented harms. Although a recent study of nearly 700 000 emergency department visits in Canada found that opioid prescriptions were not associated with increased overdoses or deaths,[6] this conflicted with previous studies that found clear links between emergency department opioid prescriptions, dependence, overdose, and death.[7,8] In the US, around 15 000 deaths per year are attributed to prescription opioids;[9] in Canada, 53 821 deaths were apparently related to opioid toxicity between 2016 and 2025.[10]

Low-value care for low back pain is prevalent across many health systems. Among US Medicare beneficiaries, nonindicated lumbar imaging was the fifth most common low-value service from 2018 to 2020.[11] In Canada, advanced imaging for low back pain has been used as an exemplar of low-value care. One analysis of 3 exemplar low-value services in Canada found that advanced imaging for low back pain had the highest level of variation in use (range 0.8% to 32.6%, $n = 271\,588$ encounters; coefficient of variation = 0.59).[12] Moreover, a 2022 report from the Canadian Institute for Health Information found 24% to 31% of patients with low back pain received imaging despite not having any clinical indications, and these rates were not declining.[13] The situation is similar in Australia, where rates of low-value imaging do not seem to be changing over time[14] and where 30% to 40% of all lumbar imaging requests in the emergency department are low value.[15] Despite evidence for lack of effectiveness and substantial risk of harm, opioids are frequently used to manage low back pain.[16] Australian, American, and Canadian studies have found that approximately 60% of patients with low back pain received opioids while in the emergency department,[17] and 24% to 32% were discharged home with opioids.[6–8]

Traditional approaches to reducing low-value care, such as guideline dissemination, have had limited impact on practice. Several reasons for this have been well documented, beyond knowledge of best practice care.[18–21] In busy emergency departments, clinicians often focus on patient comfort and rapid exclusion of serious pathology.[22] Perceived patient expectations, time pressure, and fear of missing serious pathology can be key drivers of low-value care among clinicians.[22] Both clinicians and patients can hold beliefs about the value of imaging and opioids for managing low back pain, which could further drive overuse.[23] Recent evidence suggests a tendency among patients to desire at least some treatment for low back pain over nothing, even when the likely effect on pain is very small.[24] Clinicians have also shown a tendency toward "doing something" for low back pain even when they believe there would be no clinical benefit. One study in a US Department of Veterans Affairs health care system found that almost all of the 579 clinicians surveyed agreed that imaging had no clinical value for nonspecific back pain, yet more than half would still order unnecessary imaging to avoid patient dissatisfaction.[25] Such complex contextual factors suggest traditional knowledge translation approaches are unlikely to change practice.

Several behavioural strategies have been developed to harness the psychological and context-dependent drivers of clinical decision-making. Among these, behavioural nudges aim to improve clinical decisions by changing the decision environment at the point of care without restricting patient or clinician autonomy or increasing workload.[26] Nudges have been used to improve adherence to medication, uptake of screening, and evidence-based care.[27] Although nudges have shown some success,[28–30] most studies come from settings in the US and focus on increasing underused care.[31] Trials evaluating efforts to reduce overuse are less common and often limited to clinician-directed strategies.[31–35] Early findings suggest that nudges targeting both patients and clinicians may be more effective than either alone.[36]

We aimed to determine the effectiveness of nudges to reduce low-value care for patients with low back pain in the emergency department (NUDG-ED). We hypothesized that patient nudges (implemented as electronic information displays in waiting rooms), and clinician nudges (implemented as electronic health record [EHR] alerts triggered by imaging requests and opioid administration), alone or in combination, would reduce use of low-value care, defined as use of nonindicated imaging, prescription of opioids at discharge, or both.

Methods

Study design

We designed NUDG-ED as a 2 × 2 factorial, open-label, before-after, cluster randomized controlled trial (RCT) to evaluate behavioural nudges to reduce low-value care for patients with low back pain in emergency department settings. The design, randomization, and interventions are detailed in the trial protocol (Appendix 1, Supplement 1, available at www.cmaj.ca/lookup/doi/10.1503/cmaj.251595/tab-related-content).[37] We included all patients presenting to the emergency department with low back pain during the study period. A subset of patients gave written informed consent to provide patient-reported outcomes.

Setting

We conducted the RCT across 8 public hospital emergency departments in 3 local health districts in Sydney, Australia (South Western Sydney, Nepean Blue Mountains, and Western Sydney). These hospitals serve a socioeconomically and culturally diverse population of about 4 million people. Each local health district used a version of the same EHR system (Cerner Millennium). Emergency departments in Australia are typically part of hospitals in a publicly funded health care system, with no out-of-pocket cost to eligible patients. Care is led by fellows of the Australasian College for Emergency Medicine, with other providers including prevocational training doctors (typically postgraduate years 1 to 3), specialist trainees (postgraduate years ≥ 4), career medical officers, and nonmedical practitioners, including nurse practitioners and physiotherapists. Australian emergency departments use the Australasian Triage Scale to prioritize patients according to the urgency of their condition, with category 1 (life-threatening) patients seen immediately on arrival, whereas category 5 (nonurgent) patients are seen within 2 hours.

Participants

All clinicians working in participating emergency departments during the trial period were automatically enrolled. Patients presenting with back pain were eligible if they were aged 18 years or older and received a diagnosis of musculoskeletal back pain (details available in Appendix 1, Supplement 1).

Interventions

Our nudge interventions aimed to improve decision-making by reshaping the emergency department environment for patients and clinicians. This included adjusting waiting areas and order systems, suggesting preferred care alternatives, and attempting to disrupt entrenched habits at the point of care. Further details

of the intervention components and underpinning behavioural theories are available in our published protocol.[37]

Patient nudges

Six information posters were displayed on large, newly installed 55-inch advertising screens in emergency department waiting rooms. The screen was positioned in a location that faced most of the people in the emergency department waiting room. Three of the 6 posters focused on communicating that imaging is rarely helpful for most patients with low back pain and can lead to harm. A fourth poster encouraged shared decision-making by prompting patients to ask their clinician whether imaging was necessary, what the risks were, and what might happen if the test were not performed. The remaining 2 posters focused on medicines. The first poster emphasized that nonsteroidal anti-inflammatory drugs (NSAIDs) provide similar pain relief as opioids, with fewer adverse effects. The second reassured patients that their clinicians were committed to delivering safe and effective care for patients with back pain (Appendix 1, eFigure 1). All posters included a quick-response (QR) code linked to a brochure with further information about imaging, opioids, and evidence-based alternatives for managing low back pain (Appendix 1, eFigure 2). The patient nudges were developed following qualitative studies with clinicians and patients,[38,39] designed by advertisers, and tested in a pilot study.[40] Messages were then updated with input from emergency department clinicians, consumer advisors, and a behavioural economist (G.A.). Posters were translated into Arabic, Simplified Chinese, and Vietnamese. All 6 posters — in English and in the top 2 languages at each hospital — were displayed in a continuous slideshow, with each poster shown for 20 seconds. The posters rotated throughout the day between 6 am and 10 pm.

Clinician nudges

Three EHR decision support alerts were designed to interrupt low-value clinical practices and guide clinician behaviour. The first alert was triggered when a request for lumbar spine imaging was submitted in the EHR for a patient who had presented with back pain. It reminded clinicians that imaging is not recommended for low back pain unless specific clinical indications are met. The alert listed these indications and linked to additional resources and a conversation guide to support clinicians to discuss care options with their patient (Appendix 1, eFigure 3). It also aimed to reduce clinician uncertainty and safety concerns by clarifying appropriate imaging thresholds.[41] The clinician could choose not to proceed with the imaging request after seeing the alert. The second alert was triggered when a request was made in the EHR for administration of opioids for patients who presented with back pain, prompting clinicians to consider NSAIDs as a first-line alternative (Appendix 1, eFigure 4). To reduce alert fatigue, this nudge was temporarily muted if the same clinician had already administered an opioid to the same patient within the previous 2 hours. As with the imaging alert, clinicians could choose to proceed or cancel after reviewing the message. The third alert was triggered when a clinician saved or submitted a discharge summary form for a patient with a diagnosis code corresponding to nonspecific low back pain (Appendix 1, eFigure 5). This message encouraged clinicians to provide self-management advice (e.g., heat packs, movement, simple analgesia) and reinforced that opioids are not recommended (Appendix 1, eFigure 5). These opioid alerts aimed to highlight the availability of preferred care options.[42–44]

Box 1: Criteria for an appropriate diagnostic imaging request for low back pain

- Treating clinician documented a suspicion of serious spinal pathology (fracture, cauda equina syndrome, infection, or malignancy) before the imaging request
  OR
- Treating clinicians documented any of the following clinical features before the imaging request:
  - new bladder or bowel disturbance, saddle numbness, or lower motor neuron weakness (increases suspicion of cauda equina syndrome);
  - new onset of fever and history of intravenous drug use, recent spinal procedure, or immunosuppression (increases suspicion of spinal infection);
  - major risk factors for cancer, including a history of cancer that metastasizes to bone (e.g., breast, lung, prostate) or new onset of low back pain with history of cancer (increases suspicion of vertebral malignancy);
  - major risk factors for vertebral compression fracture (history of osteoporosis, systemic long-term steroid use, serious trauma, older age [> 65 yr for males, > 75 yr for females]), high-force trauma, or minor trauma in older adults [> 65 yr for males, > 75 yr for females]).

Patient involvement

We codesigned the nudges with both patients and emergency department clinicians. Two patient advisors were involved in the protocol development, including the design of interventions, selection of outcomes, and review of patient-facing materials. One advisor (K.T.) remained involved throughout the RCT and provided critical input in interpreting the findings.

Outcome measures

Our primary outcome was the proportion of emergency department encounters for low back pain that included low-value care. Low-value care was defined as nonindicated lumbar spine imaging, an opioid prescribed at discharge, or both. We chose this composite outcome because it was a meaningful metric to emergency department clinicians. We excluded opioid administration within the emergency department from our measure of low-value care, as clinician perspectives on its value for individual patients with low back pain varied, while clinicians agreed that prescribing opioids at discharge from the emergency department for musculoskeletal back pain was low-value care.

We assessed primary outcomes through chart review by emergency department clinicians using previously validated methods.[15] Reviewers identified cases where imaging lacked a clinical indication and where opioids were prescribed at discharge for nonserious low back pain. We considered imaging to be indicated based on criteria from the American College of Physicians[45] and from discussion with emergency department clinicians. The criteria for appropriate imaging are listed in Box 1 (Appendix 1, eFigure 6, provides decision trees used by chart reviewers).

As a secondary objective, we examined effects on the 2 components of our composite primary outcome separately (nonindicated imaging and opioids prescribed upon discharge), health service outcomes, and patient-reported outcome measures. Health service outcomes included hospital admission rates, length of stay in the emergency department, and administration of opioids and NSAIDs, as recorded in the EHR. Patient-reported outcomes captured patients' experiences of care, pain intensity, quality of life, and beliefs about the benefits of imaging and opioids. These were collected through follow-up surveys sent via text message to the patient's mobile phone number, up to 1 week after emergency department discharge. Our key measure to determine whether patient experience was noninferior with exposure to either nudge intervention was the Overall Assessment of ED Experience scale of the Press Ganey Survey (range 1 to 5).[46] We also monitored unintended consequences, including repeat emergency department presentations and patients leaving without treatment.

Randomization and blinding

A statistician (Q.L.) generated the randomization schedule using computer-based assignment. Emergency departments were stratified by hospital size and randomized in a 2 × 2 factorial design into 1 of 4 arms: patient nudge only (2 hospitals), clinician nudge only (2 hospitals), both patient and clinician nudges (2 hospitals), or no nudges (2 hospitals).

All investigators and sites were blinded to group assignment until 2 weeks before launch of the intervention. At that point, the lead investigator and clinical trial team (A.C.T., S.S., G.A., A.v.W.) were unblinded to enable implementation. As this was an open-label trial, site investigators and emergency department directors were unblinded 1 week before intervention launch. Directors were asked to notify their emergency department clinicians about the trial, its aims, and the intervention components. This email was used to demonstrate leadership support for the RCT, mitigate potential backlash from clinicians receiving decision alerts, and ameliorate Hawthorne effects biasing our primary outcome by informing control sites that their performance was also being monitored.[47] Randomization details and communication to emergency department clinicians are available in the trial protocol (Appendix 1, Supplement 1).

Implementation

The intervention ran for 6 months, from Aug. 13, 2024, to Jan. 28, 2025, following a 3-month baseline period (May 15 to Aug. 12, 2024). Patient and clinician nudges were implemented simultaneously at their assigned sites. Patient nudges were activated remotely via an online dashboard managed by the RCT team. Screens were remotely monitored, and any site appearing offline triggered follow-up with emergency department staff. Clinician nudges were implemented by each health district's EHR management team. When the intervention period commenced, the RCT team verified that posters and alerts were active at intervention sites and absent from control sites. To monitor intervention fidelity and any potential problems, the RCT team conducted regular site visits in the 3 months before launch, during the first week of the intervention, and monthly thereafter, throughout the 6-month intervention period. At the conclusion of the trial, we surveyed a convenience sample of clinicians at each intervention site to capture their perceptions of the nudges.

Sample size

We estimated that a minimum total sample size of 2416 encounters for low back pain across 8 sites over a 3-month baseline period and 6-month intervention period was required to detect an effect of the patient or clinician nudges on the number and proportion of encounters involving low-value care. This calculation assumed an absolute difference of 10% between groups (e.g., 30% low-value care rate in control hospitals v. 20% in intervention hospitals), 80% power, a significance level of 0.05, an intraclass correlation coefficient of 0.10, and an intraperiod correlation of 0.09 (i.e., between the baseline and intervention periods within each site), and accounted for variable cluster sizes. For patient-reported outcomes, we required 456 survey respondents to detect a meaningful decrease in patient experience due to either intervention. We assumed a mean of 4.2 points, a standard deviation of 1.9, and a noninferiority margin of 0.5 points (i.e., 0.5 units was the maximum acceptable decrease in patient experience).[46]

Statistical analysis

We summarized baseline characteristics of the full study sample, grouped by trial arm. Patient characteristics included age, sex, being born outside of Australia, speaking a language other than English at home, requiring an interpreter, and socioeconomic status, estimated from patients' postcodes and the Index of Relative Socio-economic Advantage and Disadvantage (IRSAD) deciles, with the first to fifth deciles representing disadvantaged areas.

The primary analysis followed a factorial design, comparing the effects of patient or clinician nudges on the proportion of encounters with low-value care. We assumed no interaction between the 2 interventions and calculated marginal estimates for each factor. That is, all hospitals allocated to receive the patient nudge ($n = 4$) were compared with those that did not ($n = 4$), regardless of whether they were assigned to receive clinician nudges (factor 1); and all hospitals that received the clinician nudge ($n = 4$) were compared with those that did not ($n = 4$), regardless of whether they were assigned to receive patient nudges (factor 2).

We estimated intervention effects as adjusted odds ratios (ORs) and marginal risk differences with corresponding 95% confidence intervals (CIs), using the factorial control group (no nudges) as the reference. The primary analysis was based on an adjusted model that included fixed effects for intervention and time (baseline period v. intervention period), a random effect for clusters (sites), and an interaction between intervention and time to account for the before–after effect. To assess time effects — that is, the difference in low-value care in the intervention period compared with the baseline period — we conducted a logistic mixed regression with hospitals as random effects to account for possible heterogeneity. The intervention effect was estimated as the adjusted OR for low-value care in the intervention period between intervention and control groups, adjusting for differences in age, sex, being born outside Australia, English language spoken at home, socioeconomic disadvantage, and back pain category (nonspecific, neurologic signs and symptoms, or serious spinal pathology). To

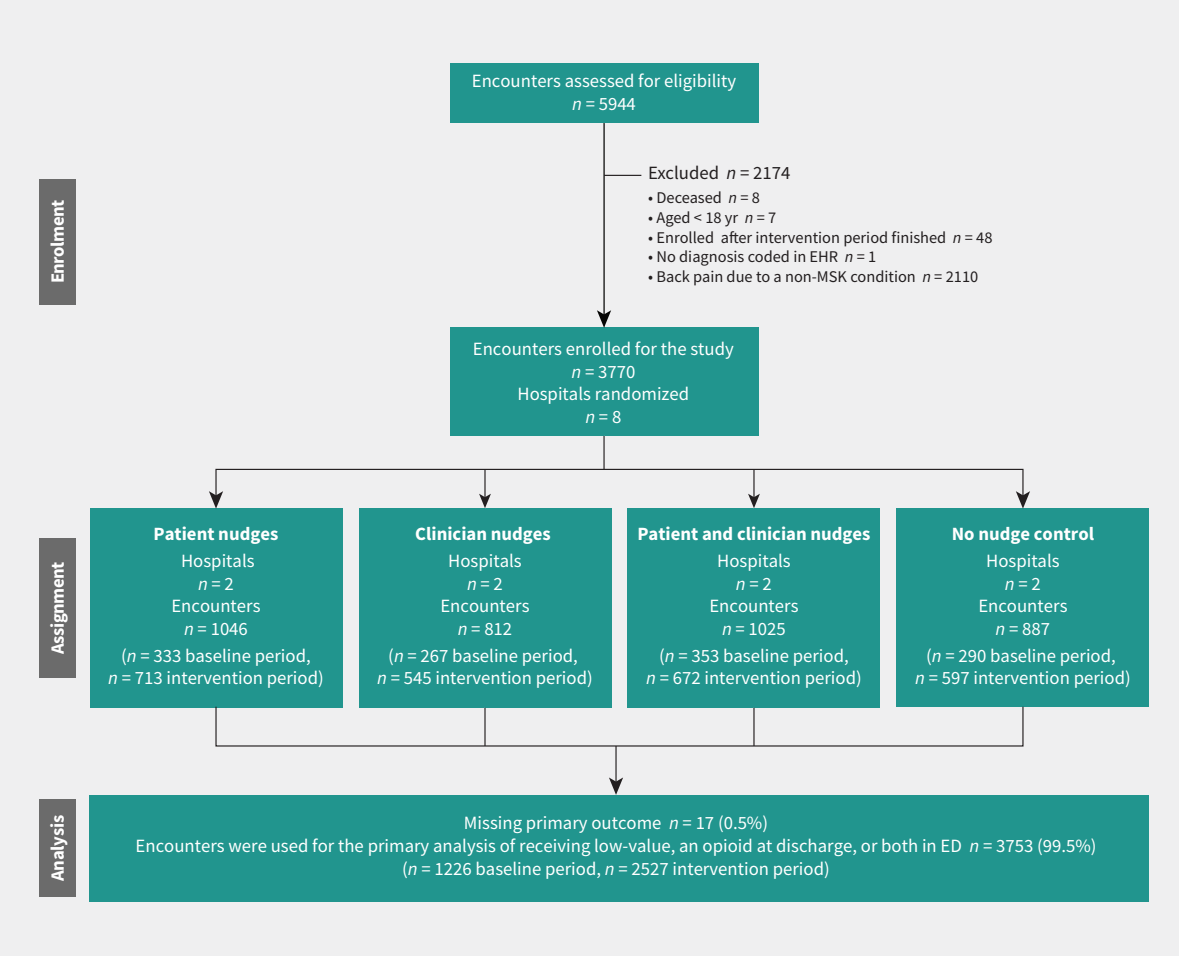

Figure 1: Patient flow diagram. For analyses, we grouped intervention period encounters by those who received patient nudges (patient nudges only + patient and clinician nudges, *n* = 1385), those who received clinician nudges (clinician nudges only + patient and clinician nudges, *n* = 1217), no patient nudges (clinician nudges only + no nudges, *n* = 1142), and no clinician nudges (patient nudges only + no nudges, *n* = 1310). Note: ED = emergency department, EHR = electronic health record, MSK = musculoskeletal. See Related Content tab for accessible version.

assess the potential impact of repeat presentations (around 10% of patients had multiple eligible visits), we conducted a sensitivity analysis excluding duplicate patient encounters to evaluate whether clustering at the patient level influenced results.

To explore interaction effects of the patient and clinician nudges, we conducted an analysis testing for interaction between the 2 interventions. We added a 3-way interaction term (patient nudge × clinician nudge × time), along with their 2-way interactions, to the primary model to explore potential interaction effects during the intervention period. We analyzed secondary outcomes descriptively using the same encounters defined in the primary analysis. Further details are available in the preregistered statistical analysis plan (Appendix 1, Supplement 2).

Ethics approval

This study was approved by the South Western Sydney Local Health District Human Research Ethics Committee (no. 2023/ETH00472).

Results

Patient characteristics

Of the 5944 patient encounters assessed, 3770 were enrolled and 3753 included in the primary analysis (Figure 1). The mean patient age was 50 years, 52.4% of encounters were for female patients, 46.4% of patients resided in disadvantaged areas, 17.5% reported speaking a language other than English at home, and 7.7% required an interpreter (Table 1). Patient characteristics such as age and sex were similar across intervention group; however, some cultural and socioeconomic variables varied between groups.

Primary outcome

During the baseline period, the overall prevalence of low-value care was 41.6% (*n* = 510 of 1226 encounters) with site prevalence ranging from 20% to 53% (Figure 2). Of the total 1226 encounters, 10% (*n* = 122) involved unnecessary imaging (site prevalence

Table 1: Characteristics of the study population

Characteristic	No. (%)* of encounters				
	Patient nudges *n* = 1046	Clinician nudges *n* = 812	Both patient and clinician nudges *n* = 1025	No nudge control *n* = 887	Total *n* = 3770
Age, yr					
Mean ± SD	52.5 ± 20.1	51.9 ± 19.1	48.5 ± 18.6	48.5 ± 17.7	50.3 ± 19.0
≤ 20	31 (3.0)	15 (1.8)	29 (2.8)	12 (1.4)	87 (2.3)
21–30	133 (12.7)	105 (12.9)	152 (14.8)	130 (14.7)	520 (13.8)
31–40	200 (19.1)	151 (18.6)	225 (22.0)	227 (25.6)	803 (21.3)
41–50	160 (15.3)	140 (17.2)	199 (19.4)	146 (16.5)	645 (17.1)
51–60	153 (14.6)	134 (16.5)	146 (14.2)	139 (15.7)	572 (15.2)
61–70	127 (12.1)	102 (12.6)	111 (10.8)	116 (13.1)	456 (12.1)
71–80	130 (12.4)	96 (11.8)	96 (9.4)	60 (6.8)	382 (10.1)
81–90	90 (8.6)	58 (7.1)	58 (5.7)	53 (6.0)	259 (6.9)
> 90	22 (2.1)	11 (1.4)	9 (0.9)	4 (0.5)	46 (1.2)
Sex					
Female	574 (54.9)	393 (48.4)	555 (54.1)	453 (51.1)	1975 (52.4)
Male	472 (45.1)	419 (51.6)	470 (45.9)	434 (48.9)	1795 (47.6)
Born outside Australia	472 (45.1)	509 (62.7)	353 (34.4)	452 (51.0)	1786 (47.4)
Language other than English spoken at home	152 (14.5)	270 (33.3)	75 (7.3)	163 (18.4)	660 (17.5)
Required interpreter	77 (7.4)	162 (20.0)	25 (2.4)	28 (3.2)	292 (7.7)
Socioeconomic disadvantage†					
Yes	556 (53.2)	72 (8.9)	748 (73.0)	337 (38.0)	1713 (45.4)
No	461 (44.1)	710 (87.4)	254 (24.8)	539 (60.8)	1964 (52.1)
Interstate	0 (0.0)	0 (0.0)	8 (0.8)	3 (0.3)	11 (0.3)
Missing	29 (2.8)	30 (3.7)	15 (1.5)	8 (0.9)	82 (2.2)
Back pain diagnosis					
Nonspecific cause	957 (91.5)	711 (87.6)	926 (90.3)	765 (86.2)	3359 (89.1)
Neurologic signs and symptoms	78 (7.5)	82 (10.1)	85 (8.3)	105 (11.8)	350 (9.3)
Serious spinal pathology	11 (1.1)	19 (2.3)	14 (1.4)	17 (1.9)	61 (1.6)
Previous medical history‡					
Spinal surgery	51 (4.9)	33 (4.1)	37 (3.6)	30 (3.4)	151 (4.0)
Opioid use for back pain	157 (15.0)	117 (14.4)	111 (10.8)	85 (9.6)	470 (12.5)
Cancer	74 (7.1)	45 (5.5)	46 (4.5)	54 (6.1)	219 (5.8)
Osteoarthritis	42 (4.0)	20 (2.4)	34 (3.3)	25 (2.8)	121 (3.2)
Osteoporosis	157 (15.0)	109 (13.4)	141 (13.8)	80 (9.0)	487 (12.9)

Note: SD = standard deviation.
*Unless indicated otherwise.
†Estimated from patients' postcodes and Index of Relative Socio-economic Advantage and Disadvantage deciles.[48] Patients with a postcode outside of New South Wales (interstate) were not coded.
‡Based on manual review of emergency department triage notes.

ranging from 2% to 22%) and 35% (*n* = 434) involved opioids upon discharge (site prevalence ranging from 16% to 51%).

During the 6-month intervention period, encounters were relatively evenly distributed among the 4 intervention groups (Figure 1). Overall, there was a reduction in low-value care in the intervention period compared with the baseline period (41.6% during baseline, 37.4% during intervention; period effect: OR 0.87, 95% CI 0.76 to 1.00). Time trends did not appear to differ between groups (Figure 3).

The prevalence of low-value care in hospitals with and without patient nudges is shown in Table 2, and the prevalence of low-value care in hospitals with and without clinician nudges is shown in Table 3. Our adjusted analysis — accounting for before–after effects, cluster effects, and baseline differences in potential

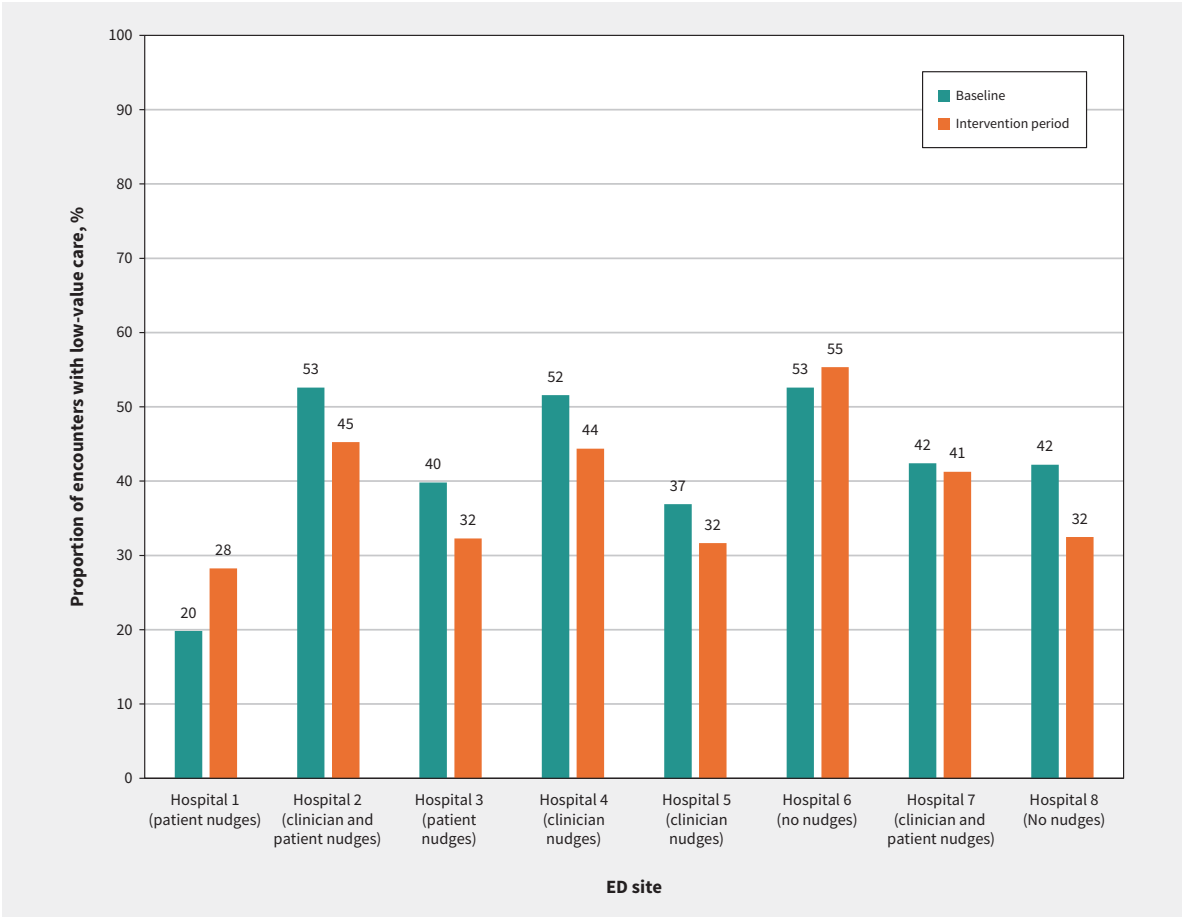

Figure 2: Proportion of encounters with low-value care for back pain, by emergency department (ED) site, during 3-month baseline period (teal) and 6-month intervention period (orange).

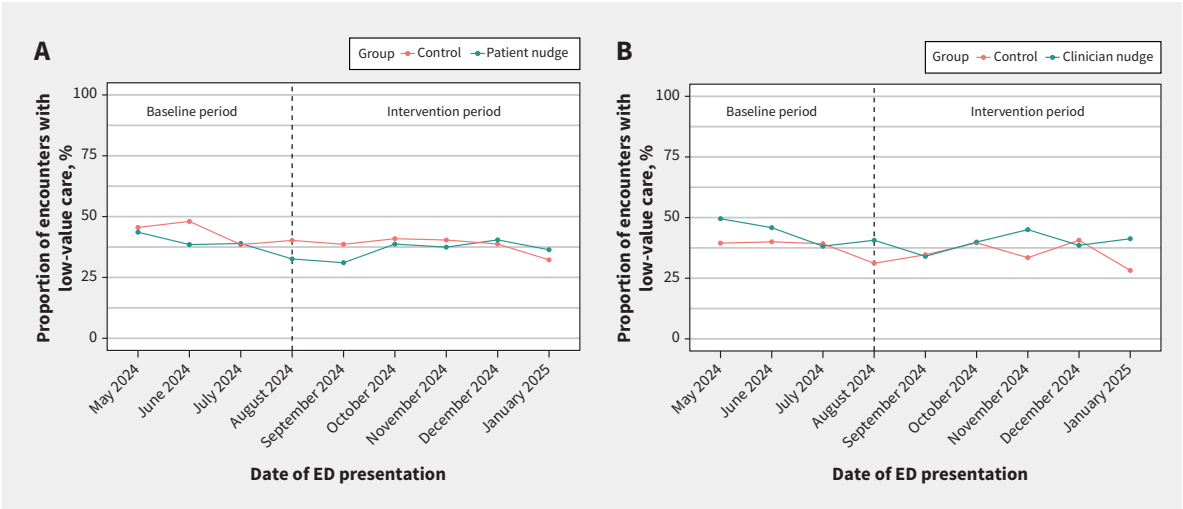

Figure 3: Proportion of encounters with low-value care for back pain per month in emergency department (ED) sites with (A) patient or (B) clinician nudges (teal) versus no nudges (orange). Dashed line indicates start of the intervention period.

Table 2: Unadjusted and adjusted effects of patient nudges on the primary outcome of low-value care and its components

Outcome	No. (%) of encounters in baseline period		No. (%) of encounters in intervention period		Effect of patient nudges		
	Patient nudge site *n* = 686	No patient nudge site *n* = 557	Patient nudge site *n* = 1385	No patient nudge site *n* = 1142	Unadjusted OR (95% CI)*	Adjusted OR (95% CI)†	Marginal risk difference OR (95% CI)‡
Low-value care (primary outcome)	267 (38.9)	243 (43.6)	504 (36.4)	435 (38.1)	0.92 (0.79 to 1.09)	0.80 (0.51 to 1.27)	−0.05 (−0.17 to 0.07)
Missing	12 (1.7)	5 (0.9)	0 (0.0)	0 (0.0)	–	–	–
Nonindicated lumbar spine imaging	71 (10.3)	51 (9.2)	130 (9.4)	106 (9.3)	1.01 (0.77 to 1.32)	1.04 (0.42 to 2.56)	−0.01 (−0.10 to 0.08)
Missing	12 (1.7)	5 (0.9)	0 (0.0)	0 (0.0)	–	–	–
Opioid at discharge	216 (31.5)	218 (39.1)	412 (29.7)	367 (32.1)	0.89 (0.75 to 1.05)	0.75 (0.54 to 1.06)	−0.06 (−0.14 to 0.03)
Missing	12 (1.7)	5 (0.9)	0 (0.0)	0 (0.0)	–	–	–
Nonindicated lumbar spine imaging and opioid at discharge	20 (2.9)	26 (4.7)	38 (2.7)	38 (3.3)	0.82 (0.52 to 1.29)	0.84 (0.33 to 2.10)	−0.01 (−0.05 to 0.03)
Missing	12 (1.7)	5 (0.9)	0 (0.0)	0 (0.0)	–	–	–

Note: CI = confidence interval, OR = odds ratio.
*Unadjusted analysis in intervention period only, not accounting for clustering or baseline period.
†Primary analysis based on an adjusted mixed model that included fixed effects for intervention and time (baseline period v. intervention period), a random effect for clusters (sites), and an interaction between intervention and time to account for the before–after effect. The intervention effect was estimated for the intervention-period comparison. To account for baseline differences, models were also adjusted on age, sex, being born outside Australia, English language spoken at home, socioeconomic disadvantage, and back pain category.
‡Based on parametric model for the marginal difference in percentages.

Table 3: Unadjusted and adjusted effects of clinician nudges on the primary outcome of low-value care and its components

Outcome	No. (%) of encounters in baseline period		No. (%) of encounters in intervention period		Effect of clinician nudges		
	Clinician nudge site *n* = 615	No clinician nudge site *n* = 611	Clinician nudge site *n* = 1217	No clinician nudge site *n* = 1310	Unadjusted OR (95% CI)*	Adjusted OR (95% CI)†	Marginal risk difference OR (95% CI)‡
Low-value care (primary outcome)	274 (44.2)	236 (37.9)	480 (39.4)	459 (35.0)	1.21 (1.02 to 1.42)	1.31 (0.84 to 2.05)	0.06 (−0.06 to 0.18)
Missing	5 (0.8)	12 (1.9)	0 (0.0)	0 (0.0)	–	–	–
Nonindicated lumbar spine imaging	67 (10.8)	55 (8.8)	100 (8.2)	136 (10.4)	0.76 (0.58 to 0.99)	0.80 (0.33 to 1.96)	−0.01 (−0.09 to 0.08)
Missing	5 (0.8)	12 (1.9)	0 (0.0)	0 (0.0)	–	–	–
Opioid at discharge	232 (37.4)	202 (32.4)	411 (33.8)	368 (28.1)	1.31 (1.10 to 1.55)	1.35 (0.93 to 1.95)	0.06 (−0.03 to 0.15)
Missing	5 (0.8)	12 (1.9)	0 (0.0)	0 (0.0)	–	–	–
Nonindicated lumbar spine imaging and opioid at discharge	25 (4.0)	21 (3.4)	31 (2.5)	45 (3.4)	0.73 (0.46 to 1.17)	0.84 (0.33 to 2.14)	−0.01 (−0.05 to 0.03)
Missing	5 (0.8)	12 (1.9)	0 (0.0)	0 (0.0)	–	–	–

Note: CI = confidence interval, OR = odds ratio.
*Unadjusted analysis in intervention period only, not accounting for clustering or baseline period.
†Primary analysis based on an adjusted mixed model that included fixed effects for intervention and time (baseline period v. intervention period), a random effect for clusters (sites), and an interaction between intervention and time to account for the before–after effect. The intervention effect was estimated for the intervention-period comparison. To account for baseline differences, models were also adjusted on age, sex, being born outside Australia, English language spoken at home, socioeconomic disadvantage, and back pain category.
‡Based on parametric model for the marginal difference in percentages.

Table 4: Patient-reported outcomes at 1 week follow-up after ED presentation, by type of nudge during intervention period

Variable	No. (%)* of respondents			
	Patient nudges *n* = 171	No patient nudges *n* = 151	Clinician nudges *n* = 155	No clinician nudges *n* = 167
Satisfaction with ED care,† mean ± SD	3.5 (1.4)	3.7 (1.3)	3.5 (1.4)	3.7 (1.3)
Likelihood of recommending ED,† mean ± SD	3.4 (1.3)	3.6 (1.3)	3.4 (1.4)	3.6 (1.3)
Health-related quality of life,‡ mean ± SD	0.6 (0.4)	0.4 (0.4)	0.5 (0.4)	0.5 (0.4)
Patient participation in decision-making,§ mean ± SD	5.1 (2.8)	5.8 (2.9)	5.4 (2.8)	5.4 (2.8)
Reassurance, mean ± SD				
Tell you that you should not be worried¶	3.4 (2.2)	4.3 (2.0)	4.0 (2.1)	3.6 (2.1)
Tell you that everything would be fine¶	3.3 (2.2)	4.2 (2.1)	4.1 (2.3)	3.4 (2.1)
Reassure you that they had no serious concerns about your back¶	3.6 (2.1)	4.4 (2.1)	4.3 (2.1)	3.7 (2.2)
How reassured do you feel that there is no serious condition causing your back pain?**	4.2 (3.2)	5.0 (3.2)	4.7 (3.2)	4.4 (3.3)
Referred to specialist††	32 (18.7)	19 (12.6)	28 (18.1)	23 (13.8)
Missing	63 (36.8)	58 (38.4)	61 (39.4)	60 (35.9)
Current pain intensity‡‡	5.9 (2.9)	6.5 (2.7)	6.1 (2.8)	6.2 (2.7)
During the past week, how much did low back pain interfere with your normal work (including both work outside the home and housework)?††				
Not at all	7 (4.1)	2 (1.3)	4 (2.6)	6 (3.6)
A little bit	8 (4.7)	3 (2.0)	8 (5.2)	5 (3.0)
Moderately	15 (8.8)	15 (9.9)	5 (3.2)	12 (7.2)
Quite a bit	34 (19.9)	24 (15.9)	24 (15.5)	26 (15.6)
Extreme	42 (24.6)	44 (29.1)	51 (32.9)	57 (34.1)
Missing	65 (38.0)	63 (41.7)	63 (40.6)	61 (36.5)

Note: ED = emergency department, SD = standard deviation.
*Unless indicated otherwise.
†Press Ganey ED Survey items[49] (1 to 5 scale), where values closer to 5 indicate better patient experience in ED. Noninferiority *p* for patient nudges = 0.02; noninferiority *p* for clinician nudges = 0.05.
‡EQ-5D-5L[50] (0 to 1 index), where values closer to 1 indicate higher quality of life.
§CollaboRATE tool[51] (0 to 10 scale), where values closer to 10 indicate higher use of shared decision-making.
¶Consultation-Based Reassurance Questionnaire items (0 to 6 scale), where values closer to 6 indicate higher perceptions of reassuring behaviour from the clinician.
** Single item from Traeger and colleagues[52] (0 to 10), where values closer to 10 indicate higher levels of reassurance about absence of serious pathology.
††Some respondents completed only part of the patient-reported outcomes survey.
‡‡Rated from 0 to 10 values, where values closer to 10 indicate worse pain.

confounders — found no effect of patient nudges on low-value care compared with no patient nudges (adjusted OR 0.80, 95% CI 0.51 to 1.27) (Table 2). Similarly, we observed no effect of clinician nudges compared with no clinician nudges (adjusted OR 1.31, 95% CI 0.84 to 2.05) (Table 3). We found no evidence of an interaction effect (Appendix 1, eTable 1). A sensitivity analysis that accounted for the 10% of encounters that were repeat presentations found no meaningful change in results.

During the intervention period, the prevalence of unnecessary imaging was 9.4% (*n* = 130 of 1385) with patient nudges versus 9.3% (*n* = 106 of 1142) without (adjusted OR 1.04, 95% CI 0.42 to 2.56), and 8.2% (*n* = 100 of 1217) with clinician nudges versus 10.4% (*n* = 136 of 1310) without (adjusted OR 0.80, 95% CI 0.33 to 1.96). The prevalence of opioid prescribing at discharge was 29.7% (*n* = 412 of 1385) with patient nudges versus 32.1% (*n* = 367 of 1142) without (adjusted OR 0.75, 95% CI 0.54 to 1.06), and 33.8% (*n* = 411 of 1217) with clinician nudges versus 28.1% (*n* = 368 of 1310) without (adjusted OR 1.35, 95% CI 0.93 to 1.95) (Table 2). We observed variability in the prevalence of low-value care between sites in the baseline and intervention periods (Figure 2). During the intervention period, unnecessary imaging ranged from 2.7% to 21% across sites, and opioid at discharge prescribing ranged from 22% to 43% across sites.

Secondary outcomes

A total of 441 (29.5%), 322 during the intervention period, of the 1492 participants invited provided patient-reported outcomes during the trial, such as patient experience and pain intensity, at 1 week after the index presentation (Table 4 and Appendix 1, eTable 2). Among respondents, patient experience

was noninferior in the groups exposed to the patient nudges versus no patient nudges (mean difference [MD] −0.13 points on 5-point scale, 95% CI −0.48 to 0.24, noninferiority $p = 0.02$), but noninferiority could not be confirmed for clinician nudges (MD −0.21, 95% CI −0.55 to 0.13, noninferiority $p = 0.05$). Around 80% of patient respondents across all groups endorsed the belief that imaging was necessary for low back pain (Figure 4). A lower proportion of participants in the patient nudge group strongly

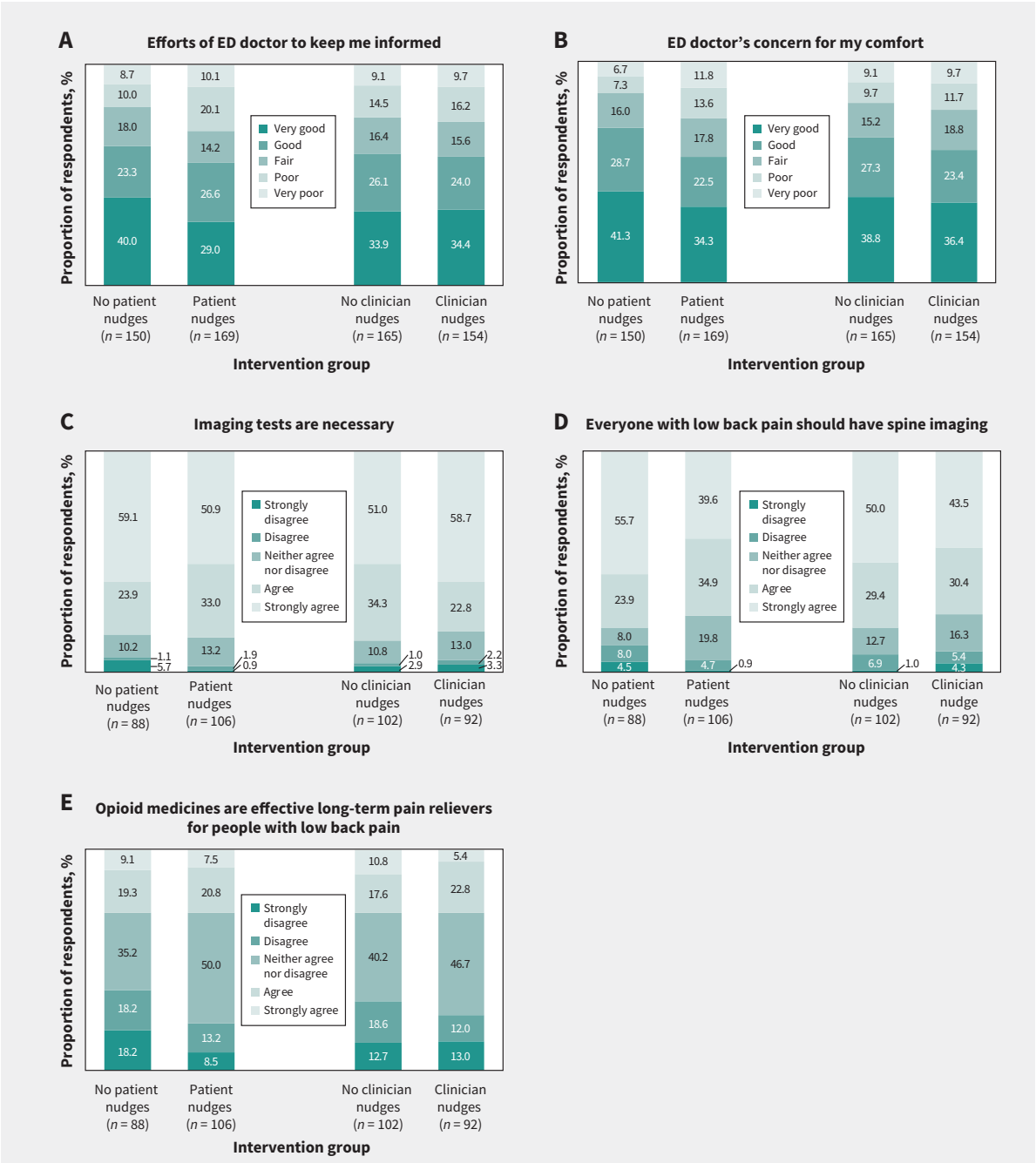

Figure 4: Measures of patient experience and beliefs, by intervention group based on patient survey. Patients rated (A) the efforts of the emergency department (ED) physician to keep them informed and (B) the ED physician's concern for their comfort. They also indicated their agreement with statements that (C) imaging (e.g., radiography, computed tomography, magnetic resonance imaging) is necessary for good care for low back pain, (D) everyone with low back pain should receive imaging, (E) and opioid medicines are effective long-term pain relievers for people with low back pain.

Table 5: Health service outcomes by type of nudge during the intervention period

Outcome	No. (%)* of encounters			
	Patient nudges *n* = 1385	No patient nudges *n* = 1142	Clinician nudges *n* = 1217	No clinician nudges *n* = 1310
Encounters with an admission to hospital	450 (32.5)	277 (24.3)	301 (24.7)	426 (32.5)
Encounters with any lumbar imaging test	418 (30.2)	331 (29.0)	340 (27.9)	409 (31.2)
Time in ED, min, mean ± SD	454.3 ± 402.6	384.6 ± 326.6	407.4 ± 342.8	437.1 ± 396.3
Encounters with an opioid medicine administered in ED	931 (67.2)	726 (63.6)	778 (63.9)	879 (67.1)
Encounters with an NSAID medicine administered in ED	737 (53.2)	676 (59.2)	721 (59.2)	692 (52.8)
Encounters where patient left without treatment	108 (7.8)	54 (4.7)	70 (5.8)	92 (7.0)
Encounters that were a 48-hour reattendance	31 (2.2)	16 (1.4)	24 (2.0)	23 (1.8)
Encounters that were a 30-day reattendance	72 (5.2)	45 (3.9)	72 (5.9)	45 (3.4)
Missing	73 (5.3)	47 (4.1)	47 (3.9)	73 (5.6)

Note: ED = emergency department, NSAID = nonsteroidal anti-inflammatory drug, SD = standard deviation.
*Unless indicated otherwise

agreed with the statement: "Everyone with low back pain should have spine imaging" (39.6% in the patient nudge group strongly agreed v. 55.7% in the no patient nudge group (16.1% absolute difference, unadjusted risk ratio 0.71, 95% CI 0.53 to 0.96). As a secondary outcome, we also explored medicine administration in the emergency department during the intervention period and found no important differences between the 2 nudge groups and their no-nudge comparators (Table 5). We found no meaningful differences in other health service or patient-reported outcomes.

Intervention fidelity

All intervention sites successfully launched on time, as planned. During the intervention period, 842 imaging alerts and 3479 opioid alerts appeared at our clinician nudge sites. Twelve of 27 (44%) emergency department clinician survey responders in the clinician nudge group recalled seeing the NUDG-ED alerts, of whom 11 reported finding them helpful or very helpful. One clinician reported finding the alerts very unhelpful, because they had appeared for patients with clear indications for imaging or those with a history of long-term opioid use. In our informal discussions with emergency department clinician participants, several could recall a previous case of missed cauda equina or septic discitis in their department, and cited this as a potential barrier to reducing use of imaging. Patient nudges were displaying correctly on the advertising screens at 96 of our 99 site checks during the intervention period. Sixty patient survey respondents answered the question about the nudge posters. Of these, 21 (35%) recalled seeing the patient nudges. There were 124 accesses of the brochure via the QR code during the 6-month intervention period.

Interpretation

We designed, implemented, and evaluated patient and clinician nudges to reduce low-value care for patients with low back pain in emergency departments from 3 broad, socioeconomically and culturally diverse regions. Neither the patient information on waiting room displays nor the electronic alerts for clinicians achieved clinically important reductions in low-value care over a 6-month intervention period. We used comprehensive methods to determine appropriateness of care through clinician chart reviews and collected patient-reported outcomes.

Our patient nudges in emergency department waiting rooms, highlighting the lack of benefits and the harms of unnecessary imaging and opioids, had no impact on low-value care. Outside of emergency care settings, systematic reviews of similar approaches to waiting room messages have found they can improve awareness of health messages, but robust evaluations are rare.[53,54] In our study, a substantially higher proportion of patients across all groups endorsed the belief that imaging was necessary for low back pain than what has been reported in primary care (i.e., around 80% in our RCT v. around 50% in a study in primary care).[55] This illustrates the challenge of shifting beliefs about imaging in emergency department settings.

Fewer patients in the patient nudge group strongly agreed that imaging was necessary for everyone with low back pain compared with the no patient nudge group. These differences are based on a subset of patient participants and may be at risk of selection bias. Moreover, fewer than half of the survey respondents reported seeing the poster, suggesting limited reach and engagement. Our data suggest that, although it might be possible for a nudge to shift some patient attitudes, this may not ultimately influence care.

The impact of our clinician nudges may have been moderated by concerns about missing serious pathology. The prevalence of serious spinal and nonspinal pathologies is substantially higher in emergency care settings than in primary care.[56] Indeed, emergency department clinicians cite concern about missing serious pathology as a key reason to request unnecessary imaging.[22] Several of our clinician participants mentioned

cases of missed spinal pathology in their department, such as cauda equina syndrome or septic discitis, at some point in their career. The consequences of missing serious spinal pathology may have outweighed any perceived benefit of avoiding unnecessary imaging, even with additional reminders about when imaging was clinically indicated.

Most previous studies of clinician-directed nudges have shown small to moderate improvements in patient care. A 2020 meta-analysis of 122 trials of computerized decision support (including 1.2 million patient encounters) found improvements in care ranging from 10% to 62%.[57] However, several recent well-designed RCTs testing nudges to address underuse problems — such as statin prescribing, serious illness conversations, and colorectal screening — have found limited benefits.[58–60] Additionally, most previous RCTs of clinician-directed nudges have focused on implementation of high-value care rather than deimplementation of low-value care. The latter likely requires a different approach.[48]

We tested interventions designed to be light-touch, low-cost, and scalable. Our findings suggest that changing low-value care in emergency departments likely requires approaches with higher reach and engagement from patients and clinicians. Fewer than 50% of clinicians recalled seeing the nudges. Emergency department clinicians receive many types of alerts per day to support patient safety;[61] the NUDG-ED alerts may have appeared too infrequently to capture attention. In 1 US study, for each additional reminder received per encounter, the likelihood of acceptance dropped by 30%.[62] To mitigate this, our opioid-prescribing alert was muted for repeat requests by the same clinician. However, we did not have user-level data to quantify the potential impact of alert fatigue. Additionally, few patients noticed the waiting room posters. This is perhaps unsurprising, given that many patients present to the emergency department with substantial pain and distress.[63]

Future trials of nudges in emergency settings could benefit from additional strategies to increase reach and engagement, provide reassurance, and address patient beliefs. Stronger or combined interventions that go beyond clinician and patient reminders at the point of care, incorporate audit and feedback,[64] increase availability of nondrug alternatives such as heat packs,[8] or provide formal decision aids to patients and clinicians[65] could be successful. Policy levers such as restructuring financial incentives or implementing additional approval processes for nonindicated care are also worthy of investigation.[66]

Limitations

The functionality of the EHR systems limited capacity to optimally time and target the alerts. In practice, this meant that the imaging and opioid administration alerts may have appeared after the care decision was made (e.g., the clinician was exposed to the alert after discussing imaging or opioids with the patient at the bedside). We had calculated our sample size based on a 10 percentage-point absolute difference in low-value care. In hindsight, this effect size may have been overly optimistic, given the low intensity of the intervention. We also observed higher-than-expected reductions in low-value care at some sites that did not receive nudges. This could have been caused by regression to the mean, Hawthorne effects, or both. Finally, we did not examine potential harms of the interventions, such as failure to request appropriate imaging for patients with clinical indications.

Conclusion

In this cluster RCT, behavioural nudges targeting patients with low back pain and their clinicians did not reduce low-value care in the emergency department. Our results indicate the need for more research to identify effective interventions to reduce low-value care in this complex setting.

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CHAPTER EIGHT: Discussion

Chapter Eight synthesises the thesis findings and the collective insights gained. Drawing on behavioural economic theory, the discussion proposes potential moderators that may help explain the findings within this thesis. It also provides additional insights and considerations for reducing low-value care for patients with low back pain in the emergency department and recommendations for future research.

8.1 Overview

This thesis aimed to evaluate the effectiveness of behavioural economics and nudge interventions to reduce low-value care. This was achieved by evaluating: 1) the impact of text message-based nudge interventions on patient reported outcome survey response rates in the emergency department; 2) theoretical and empirical evidence to identify behavioural economic techniques to improve patient adherence to home exercise programs; 3) evidence on the efficacy of clinician-directed default nudges to reduce overuse of tests and treatments, using rigorous synthesis methods; 4) the influence of the number of suggested care alternatives in nudges on primary care physician decisions regarding low-value care; and 5) the effect of clinician-directed and patient-directed nudges on reducing low-value care for patients with low back pain in emergency departments.

8.2 Principal findings

This thesis provides rigorous evidence that nudges are a feasible approach to de-implementation of low-value care in routine clinical care settings, though their effects vary substantially with nudge type, targeted behaviour, patient population, and clinical context. Chapter Two's nested randomised controlled trial demonstrated that text message nudges increased patient reported outcome survey response rates that could be critical to understanding the future impact of interventions to reduce low value care. A prize-draw incentive achieved an overall increase in response rates, while pro-social framing potentially enhanced participation among disadvantaged patients. Chapter Three provided physiotherapists with behavioural economic strategies that could improve adherence to home exercise programs. Chapter Four's systematic review found that default nudges can substantially reduce the overuse of tests and treatments. However, an *increase* in overuse seen in one default suggests that these approaches require careful, context-sensitive evaluation

before broader implementation. Chapter Five showed that suggested alternative nudges, offering between two to four preferred care alternatives, effectively increased choice of high-value options over low-value care in two common clinical scenarios in primary care. Finally, by contrast, Chapter Seven's major 2x2 factorial cluster randomised controlled trial, NUDG-ED, showed that neither clinician- nor patient-directed nudges reduced low-value imaging or opioid prescribing at discharge for patients with low back pain in emergency departments.

Collectively, these findings strengthen the evidence base for nudges in healthcare and demonstrate that no single nudge is likely to be universally effective. The complexity of real-world clinical care shapes nudge effects in ways that commonly cited theories of heuristics and cognitive biases cannot fully explain.[1,2] This underscores the need for researchers and practitioners to apply behavioural economic theories that are more relevant to clinical decision-making.[3]

8.3 Strengths and limitations in relation to existing research

8.3.1 Positioning these findings within the broader literature

This thesis sits at the intersection of applied behavioural economics, de-implementation and back pain research. While the novelty and scalability of nudges have fuelled considerable enthusiasm for application in healthcare, they have also generated scepticism.[3] In response to the growing interest in the use of nudges in healthcare, this thesis adopted a critical perspective to evaluate the efficacy and safety of nudges in routine healthcare. Relative to the existing literature, this thesis has both notable strengths and important limitations.

8.3.2 Strengths

This thesis has several strengths. First, the use of robust research methods enhances the reliability, interpretability, and practical relevance of its findings. Existing literature on nudges in healthcare remains dominated by observational study designs, which are prone to bias and may overestimate or misrepresent intervention effects. For example, of 89 studies included across four reviews on nudges targeting various quality improvement actions, such as increasing influenza vaccinations and reducing unnecessary antibiotic use, 66% were observational.[4-7] This thesis directly addresses these gaps, with Chapters Two, Five, and Seven employing randomised controlled designs to provide stronger causal evidence regarding the effectiveness of nudges. Additionally, prior systematic reviews of nudges in healthcare have predominantly relied on narrative synthesis or vote-counting methods to summarise effects. In contrast, Chapter Four advances the evidence base by examining the impact of default nudges on overuse through the synthesis of randomised trial data using standardised effect sizes to enable meta-analysis where appropriate, while rigorously appraising the certainty of evidence using the Cochrane GRADE framework.[8]

Second, this thesis enhanced the clinical relevance by taking a nuanced approach to measuring low-value care. A major limitation in existing de-implementation and nudge studies is the reliance on overall care utilisation rates as a measure of low-value care, with little consideration of whether tests or treatments were clinically appropriate for specific patients. For example, a systematic review of de-implementation trials in primary care found that only 12% of studies measured the appropriateness of care, and just 10% assessed health outcomes.[9] All of the studies in this thesis considered both appropriateness and patient-relevant outcomes. A key example is Chapter Seven's NUDG-ED trial which evaluated a primary outcome of

low-value care based on emergency department clinician reviews of clinician- and guideline-recommended indicators of appropriateness for all 3753 encounters.

Finally, this thesis advances patient-centred research and care by identifying effective strategies to strengthen the collection of patient reported outcomes. Across four systematic reviews synthesising 89 nudge studies, only five (6%) reported any patient-centred outcomes.[4-7] Similarly, none of the default nudge trials included in the systematic review in Chapter Four included patient reported outcomes. The absence of patient reported outcomes data in prior nudge studies has substantially limited the capacity to evaluate whether such interventions improve patient outcomes, safety, or quality of care. This thesis addressed this critical gap by i) providing evidence that behavioural economic text-message nudges may enhance patient reported outcome survey response rates (Chapter 2) and ii) showing that patient reported outcomes can be included in major trials to reduce low value care.

8.3.3 Limitations

This research in this thesis has some limitations. First, the effects seen within studies may not be generalisable across different low-value practices, patient populations or settings. For example, the NUDG-ED trial in Chapter Seven found clinician- and patient-directed nudges did not reduce low-value care for patients with low back pain in emergency departments. In emergency care settings, clinicians prioritise pain management and exclusion of serious pathology to enable safe and timely discharge, which could in part explain the lack of effect of clinician alerts.[10] Indeed, Chapter Five found that a simulated alert could change behaviour in primary care, however, these effects were observed only within clinical scenarios

Second, the clinician-directed nudges in Chapter Seven were constrained by the technological capabilities of electronic health systems in which they were implemented. In the NUDG-ED

trial, nudges were triggered whenever a clinician ordered an opioid or imaging test for a patient triaged with 'back pain,' which represented the most specific trigger the local system could support. As a result, nudges were sometimes delivered to clinicians for patients for whom they were less relevant. For example, adults over 65 years who had fallen for whom imaging may be appropriate.[11] In contrast, more contemporary electronic systems, such as the *Epic Electronic Health Record System,* can incorporate patient-level triggers, such as age, comorbidities or contraindications to enhance the targeting of nudges.[12] More targeted triggers for nudges could enhance their relevance and, in turn, their effectiveness in reducing low-value care.

Finally, the ability to conduct more detailed analysis was limited by the availability of data. For example, 12 of the 27 (44%) emergency department clinicians who responded to the NUDG-ED survey (Chapter Seven) reported recalling exposure to the electronic nudges. However, in the absence of data on the total number of eligible clinicians and individual-level exposure frequency, it was not possible to determine whether this finding reflects recall bias, lack of exposure to the alert, or limited exposure over time.

8.3 Potential moderators of clinician-directed nudges aiming to reduce low-value care

The variable effects of nudges in this thesis highlights the importance of understanding the conditions under which they succeed, fail, or even produce unintended consequences. The evidence across these chapters shows that nudges sometimes reduced low-value care, sometimes had no effect, and on one occasion increased overuse. These findings demonstrate that while nudges are often simple interventions to implement, clinical decision-making is inherently complex.[13] Examining when nudges succeed or fail provides valuable insight into how nudge strategies interact with the characteristics of the targeted low-value practice, the patient population and the healthcare setting.[14,15] The following sections integrate behavioural

economic theory and de-implementation research to identify three key potential moderators of nudge effects.

8.3.1 The 'costs' of changing behaviour may moderate nudge effects

The direct and indirect costs of changing existing care behaviours and adopting alternatives may moderate nudge effects. These costs include monetary expenses, as well as the time, effort, and cognitive load required to evaluate alternative options, discuss them with patients, and implement them in practice. In behavioural economic literature, such costs are described as "transaction costs"[16] or "friction,"[17] and have been identified as a barrier to behaviour change in de-implementation research.[18] For example, the clinician-directed nudges in the NUDG-ED trial promoted guideline-concordant alternatives, such as patient education or reassurance, but had no effect on clinician behaviour. This may be because providing education and reassurance was perceived as more time- and effort-intensive than continuing imaging or opioid orders.[19] In contrast, the recommended care options in the default nudges in Chapter Four and the suggested alternative nudges in Chapter Five demonstrated reductions in low-value care. This may in part be because alternatives closely matched existing routines and imposed minimal costs to the clinician.

8.3.2 The perceived risk of harm from de-implementing targeted low-value practices may moderate nudge effects

The decision to accept nudge recommendations to de-implement low-value practices may be moderated by the perceived risk of harm from de-implementation. "Prospect regret theory" suggests that when the perceived consequences of deviating from established care patterns are high, clinicians may anticipate greater regret from accepting a nudge recommendation than from remaining with existing practice.[20,21] This may explain why nudges were effective at

reducing low-value imaging in low-risk palliative radiotherapy but not for low back pain in the emergency department. In Chapter Four, a default nudge substantially reduced unnecessary imaging during palliative radiotherapy (risk difference -35.8%; 95% CI -41.0% to -30.0%; moderate-certainty evidence).[22] In this setting, imaging is used primarily for treatment monitoring rather than diagnosis or life-prolonging decisions, and the potential harms of omission are low.[22] By contrast, the nudge in Chapter Seven had no effect on reducing imaging for low back pain in the emergency department. In this context, the consequences of incorrectly omitting imaging are high. Missing serious but rare conditions such as cauda equina syndrome can result in permanent disability.[23]

8.3.3 The timing of de-implementation consequences may also moderate nudge effects

Many low-value practices cause harm in the long term, but short-term consequences may have greater influence on clinicians' decisions to provide low value care or not. According to the behavioural economic concept of "temporal discounting", when decisions involve trade-offs between short- and long-term outcomes, immediate consequences tend to be more influential.[24,25] In Chapter Four, a 5-tablet default slightly reduced overuse of larger opioid prescriptions in emergency care[26] but *increased* larger prescriptions in dentistry.[27] Although opioids in both contexts carry similar long-term risks, such as dependence and overdose, the perceived short-term consequences of accepting the default differed between contexts.[28] In dentistry, clinicians may have been concerned that a 5-tablet prescription would be insufficient to treat post-procedural pain, potentially resulting in repeat visits, delayed recovery, or reduced patient trust.[29] Conversely, a 10-tablet default achieved significant reductions in prescriptions for large packs of opioids in dentistry,[27] primary and emergency care,[26] potentially because the perceived short term harms of accepting the default quantity were considered acceptable.

8.3.4 Clinical and contextual factors may limit nudge effectiveness for low back pain in emergency departments

Low-value care, including unnecessary imaging and opioid prescribing for patients with low back pain, remains prevalent in Australian emergency departments. The clinician- and patient-directed nudges evaluated in NUDG-ED (Chapter Seven) were novel, behaviourally informed and co-designed strategies that provided decision-relevant information at the point of care and in the waiting room. Their implementation at the point of care aimed to gently disrupt entrenched clinical habits and support clinicians by providing timely guideline concordant information and guidance. Despite these strengths, neither intervention reduced overuse of imaging or opioid prescribing at discharge.

The limited impact of the interventions in NUDG-ED may in part reflect the complexity of managing back pain in emergency departments. Patients often present with severe, escalating pain and frustration from unmet primary care needs.[30] An Australian study of 90 patients with chronic neuromusculoskeletal pain found that low health literacy, socioeconomic disadvantage, limited social support, and traumatic experiences worsened symptoms and increased care use.[31] Nearly half of NUDG-ED participants were from disadvantaged areas, highlighting their vulnerability and complex needs. Australian emergency care clinicians report feeling confident managing acute pain but find chronic or recurrent pain far more complex and difficult to treat effectively within the emergency care environment.[19] In this context, reducing imaging and opioids, even when clinically appropriate, may feel at odds with clinicians' desire to provide the comprehensive care, within the existing constraints, to meet patients physical and psychological needs.[32,33]

Additionally, patient heterogeneity and varying clinical risks complicate efforts to reduce low-value care in emergency departments. For example, although opioids are often classified as

low-value due to well-documented risks, deprescribing in the emergency department may unintentionally harm some patients.[34] Clinicians may have well-founded concerns about withdrawing opioids from patients who are already using them.[35] Moreover, the recommended alternative of non-steroidal anti-inflammatory drugs, may be contraindicated or carry serious risks for older people, such as gastrointestinal bleeding.[11] These complexities present a clear challenge for interventions aimed at reducing low-value medicines in emergency departments.

8.4 The future of using nudges to reduce low-value care

Considering the moderators and limitations discussed, the following nudge approaches may merit evaluation to reduce low-value care.

8.4.1 Nudges may be more effective when they support patient-centred care

When clinical practices can be either low-value or high-value depending on the patient, nudges may be more effective and appropriate when targeted to individuals for patients the care is most likely low-value for. For example, a recent U.S. trial used more precise inclusion and exclusion criteria for both patients and clinicians to trigger an electronic nudge aimed at reducing overuse of medications in older adults.[36] Primary care physicians were eligible if, in the previous 180 days, they had prescribed at least one benzodiazepine or non-benzodiazepine sedative-hypnotic, or at least two anticholinergic medications, to a patient aged 65 years or older. Patients were eligible if they were aged 65 years or older and had been prescribed at least 90 pills of a targeted medication within the same 180-day period. The intervention increased the likelihood of deprescribing by 40% compared with usual care (relative risk, 1.40; 95% CI: 1.14 to 1.73), corresponding to an absolute increase of 10.4 percentage points.

A limitation in Chapter Seven's clinician-directed nudges was the inability of existing emergency department electronic health systems to implement such precise inclusion or

exclusion criteria, triggering nudges broadly for any "back pain" patient. However, from 2026 New South Wales emergency departments are implementing a more contemporary electronic health system[37] that will facilitate more clinically relevant triggers. In systems where targeted triggers are not feasible, nudges should be designed to accommodate patient heterogeneity. For example, nudges aiming to reduce opioid harms should follow deprescribing guidelines by encouraging lower opioid dose or quantities when alternatives are contraindicated.[38] Suggested-alternative nudges could offer lower morphine milligram equivalent options as well as non-opioid analgesics, while default nudges could encourage lower dose or quantity. Engaging clinicians and patients in selecting appropriate options and settings may further enhance nudge effectiveness.[13]

8.4.2 Nudges could incorporate patient-reported outcomes to improve clinician perceptions of short-term outcomes

One potential moderator of nudge effects is clinicians' perception of short-term harms from de-implementing a low-value practice. Nudges could mitigate these concerns by providing feedback on patient outcomes. As illustrated in Chapter Four, a 5-tablet default nudge for opioid prescriptions increased the use of larger prescriptions, potentially because clinicians perceived 5 tablets as insufficient to adequately treat patients. Patient-reported outcomes on post-discharge tablet use and recovery can help address clinicians' concerns about undertreatment. In a 2025 stepped-wedge trial, nudges providing clinicians with feedback on patients' post-discharge pain levels and number of tablets used after surgery significantly improved guideline-concordant prescribing (57.2% vs. 71.8% guideline-adherence; adjusted difference 5.3%; 95% CI: 2.0 to 8.7%; P = 0.002; n = 20,557 patients).[39] A subsequent qualitative evaluation found that clinicians were motivated by a desire to ensure patients could appropriately manage pain following discharge.[40] Clinicians reported valuing feedback on

patients' pain and medication use, with one describing the information as "reassuring and helpful." This feedback supported clinicians to reduce prescribing quantities without concern about undertreating pain.[40] By integrating patient-reported outcomes, nudges could align clinician perceptions with real patient experiences, improving acceptance and implementation of recommendations.

8.4.3 Nudges could improve clinicians' perceptions of long-term harms of clinical decisions

Nudges could help raise awareness of the potential long-term harms of continuing low-value care. For example, a 2018 cluster randomised trial (n = 861 clinicians; 1,279,691 prescriptions) sent clinicians a letter informing them of a patient's fatal opioid overdose, along with guidance on safer prescribing.[41] This nudge produced substantial reductions in opioid prescribing (from 72.5 to 65.7 morphine milligram equivalents [MME] per prescription; -6.8 MME; 95% CI: -9.9 to -3.8) and reduced new opioid initiations, with clinicians 7% less likely to start opioids for a new patient than controls (95% CI: 2% to 11%; $P < 0.001$).[41] Providing this feedback, even on the sensitive issue of patient death, enables clinicians to make more informed judgments to reduce long-term harms, and uphold their fundamental ethical commitments to patient well-being, continuous learning and professional accountability.[42]

8.5 Conclusion

This thesis provides robust evidence on the potential for, and limitations of, nudges to reduce low-value care. The findings suggest that nudges are feasible to implement and can influence low-value care in some contexts, though effects may be unexpected and are not universally appropriate, effective, or safe for all clinical decisions. Collectively the findings revealed potential moderators that could help explain variation in effects on low-value care, deepen understanding of clinical decision-making, and guide the design of future nudge interventions.

As nudges become more widely used in healthcare, this thesis emphasises the importance of using rigorous trial designs, measuring appropriateness carefully, and considering patient-centred outcomes.

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APPENDICES

Appendix One: Chapter Two metrics and supplementary materials

Appendix Two: Chapter Three metrics

Appendix Three: Chapter Four metrics and supplementary materials

Appendix Four: Chapter Five metrics and supplementary materials

Appendix Five: Chapter Six metrics and supplementary materials

Appendix Six: Chapter Seven metrics and supplementary materials

Appendix One: Chapter Two metrics and supplementary materials

Metrics

The paper presented in Chapter Two has been accepted at the Journal of Clinical Epidemiology which has an impact factor of 5.2 and is a Q1 for Medicine and Epidemiology. The Scimago Journal and Country Rank (2024) is 3.149 and has a H-Index of 262.

Citation

Altinger G, Sharma S, Li Q, et al. *Text message incentives increased patient-reported outcomes survey response in emergency care: SWAT findings* 2025 Journal of Clinical Epidemiology doi: 10.1016/j.jclinepi.2025.112116

Chapter Two supplement

Pre-registered protocol: Using behavioural cues to increase response rates to a patient-reported outcomes survey: protocol for an experimental study nested in a cluster randomised trial

Gemma Altinger, Swee Sharma, Qiang Li, Aidan Van Wyk, Caitlin Jones, Chris Maher, Adrian Traeger

Background

Low back pain is under-researched in the emergency department (ED).(1, 2) In particular, studies of patient-reported outcomes and experiences following an ED visit are rare. This could be due in part to difficulty recruiting study participants. Identifying methods to enhance recruitment, especially for trials embedded in routine care, could optimise research in ED.(2) Behavioural cues included in trial invitations could increase response rates. A Cochrane review found evidence that invitations which included a financial incentive doubled the odds of participants completing or partially completing a mailed questionnaire.(3) Highlighting the positive impact a study participant's responses could make to future patients ('pro-social' cue) may also increase response rates.(4)

Previous research has typically been conducted under lab conditions or using mailed surveys. It is unclear whether these behavioural approaches lead to an increased response rate when study invitations are sent via an SMS message to people who recently attended the ED.

Aim

To determine whether adding a financial incentive to a study invitation can increase the response rate to a patient survey compared with a standard study invitation. Secondary aims are: 1) determine whether a pro-social cue increases the response rate compared with a standard invitation, and 2) determine whether financial incentives are more effective than a pro-social cue at increasing the response rate.

Methods

Study design

A 3-arm randomised study nested within a cluster randomised controlled trial.

Study setting

The study will be conducted in eight hospital emergency departments (Liverpool Hospital, Campbelltown Hospital, Bankstown Hospital, Westmead Hospital, Fairfield Hospital, Nepean Hospital, Blacktown Hospital and Mt Druitt Hospital) across three local health districts in Sydney (South Western Sydney Local Health District, Western Sydney Local Health District, and Nepean Blue Mountains Local Health District).

Participants and recruitment

Participants will be patients with low back pain due to a musculoskeletal condition who presented to an emergency department participating in the NUDG-ED randomised trial.(5) In the NUDG-ED trial, a subset of patients who present to the emergency department with back pain are invited to complete a patient survey. The invitation is sent via a short message service (SMS) on behalf of clinical staff at the hospital, using a program called Twilio. Patients are eligible for the survey if they were diagnosed with low back pain due to a musculoskeletal condition, did not require an interpreter, and did not opt out of the study in the emergency department waiting room.

Randomisation

Participants will be randomised to one of three groups using the randomisation feature in REDCap: i) Message A; ii) Message B; iii) Message C.

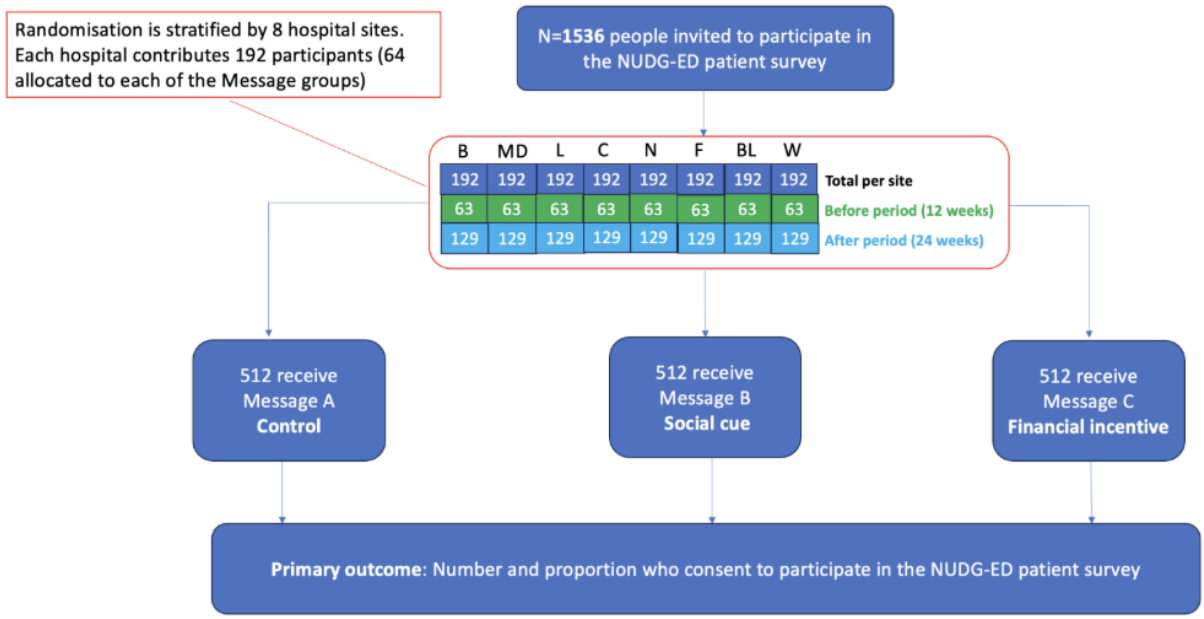


Figure 1: Study design. Columns in red box indicate 8 individual hospital sites ("B", "MD", "L" etc are codes for hospitals involved in the study)

Intervention groups

Message A [Control]

Participants will receive the following message via SMS:

Dear [PATIENT_NAME],

We hope you are going well after your recent visit to our emergency department. We are interested in what you thought of our care. This voluntary survey will only take 5 minutes to complete.

To begin the survey, visit [LINK TO SURVEY]

To opt out reply STOP or ignore this invitation.

Your responses will contribute to a study being conducted by our department and Dr Adrian Traeger from The University of Sydney.

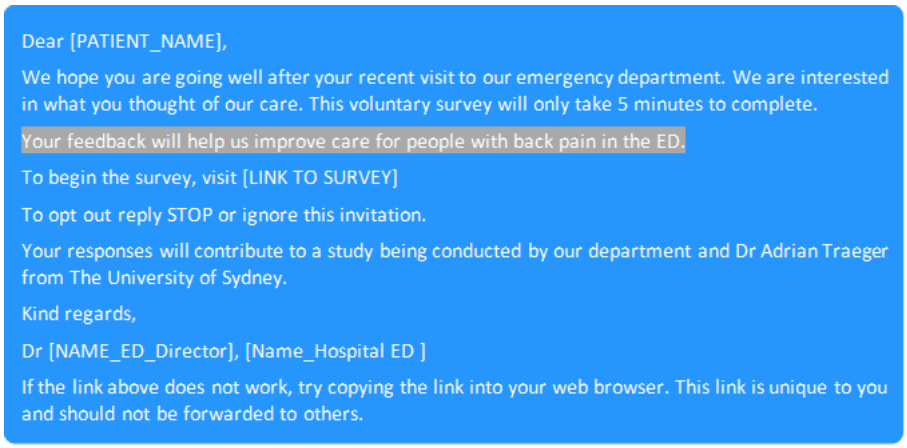
Kind regards,

Dr [NAME_ED_Director], [Name_Hospital ED]

If the link above does not work, try copying the link into your web browser. This link is unique to you and should not be forwarded to others.

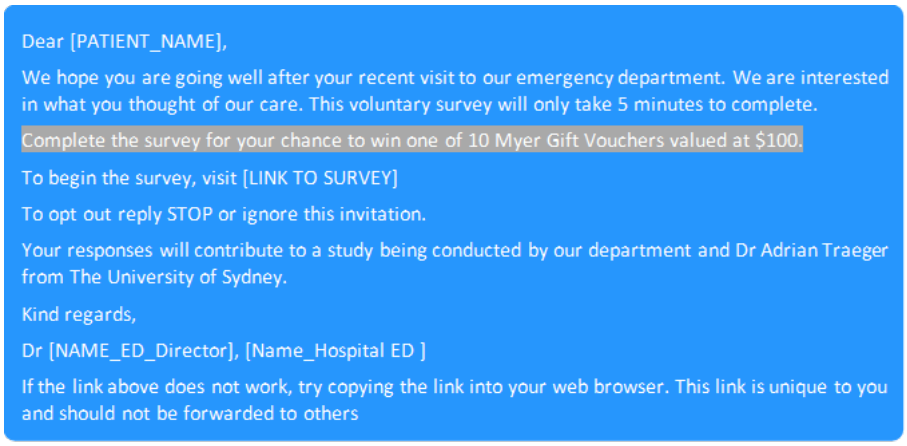
Message B [Pro-social cue]

Participants will receive the following message (pro-social cue indicated in grey highlight) via SMS:



Message C [Financial incentive]

Participants will receive the following message (financial incentive indicated in grey highlight) via SMS:



Outcome

The primary outcome will be the number and proportion of patients responding to the SMS invitation. A 'response' is considered to be completion of the consent form for the NUDG-ED patient survey. This number will be expressed as a percentage of invitations sent.

Sample size and analysis

Our previous SMS-based study(6) suggests a 33% response rate. We want to detect an absolute difference as small as 9% in our primary comparison between Message A and C. Primary analysis will be between Message A (control) and Message C (financial incentive), because Message C is the most promising based on pilot work. Additional comparisons (A vs B),(B vs C) will be exploratory. Minimal sample size is 1250, which we have increased

to 1536. Descriptive analyses will be done to report the response rate for all participants in each of the three groups. We will calculate the number and proportion of participants responding to messages and will consider exploring the influence of age, sex, ethnicity and socioeconomic status.

Ethical issues

This study has ethical approval from the Southwest Sydney Local Health District Human Research Ethics Committee (Approval ID 2023/ETH00472).

Consent

We have sought a waiver of consent for patient participants for the nested study because it is impractical and because obtaining consent would create a greater burden to patients than the intervention itself.(7) However, patients will be notified that there is a study happening and they will be able to .

Monetary incentives

Fair distribution of benefits and risks of research is one of the key principles of ethical research.(8) Participants invest their time to participate in research deserve some benefit in return.(8) We will provide this in the form of a ticket to a lucky draw to win one of 10 Myer vouchers valued at $100.

It is appropriate to provide such incentive to participants in research projects that are not risk rated as high risk, such as this project.(9) Identifiable data (ie name and phone number) will be treated as highly sensitive data per the broader NUDG-ED trial research data management plan e.g. only approved trial investigators will have access to this database. As with the main NUDG-ED and analysis, we will remove identifiers after lucky draw winners have been notified.

In running the lucky draw, we will comply with the NSW lottery laws and draws will be administered and conducted by someone independent of the research team.(9)

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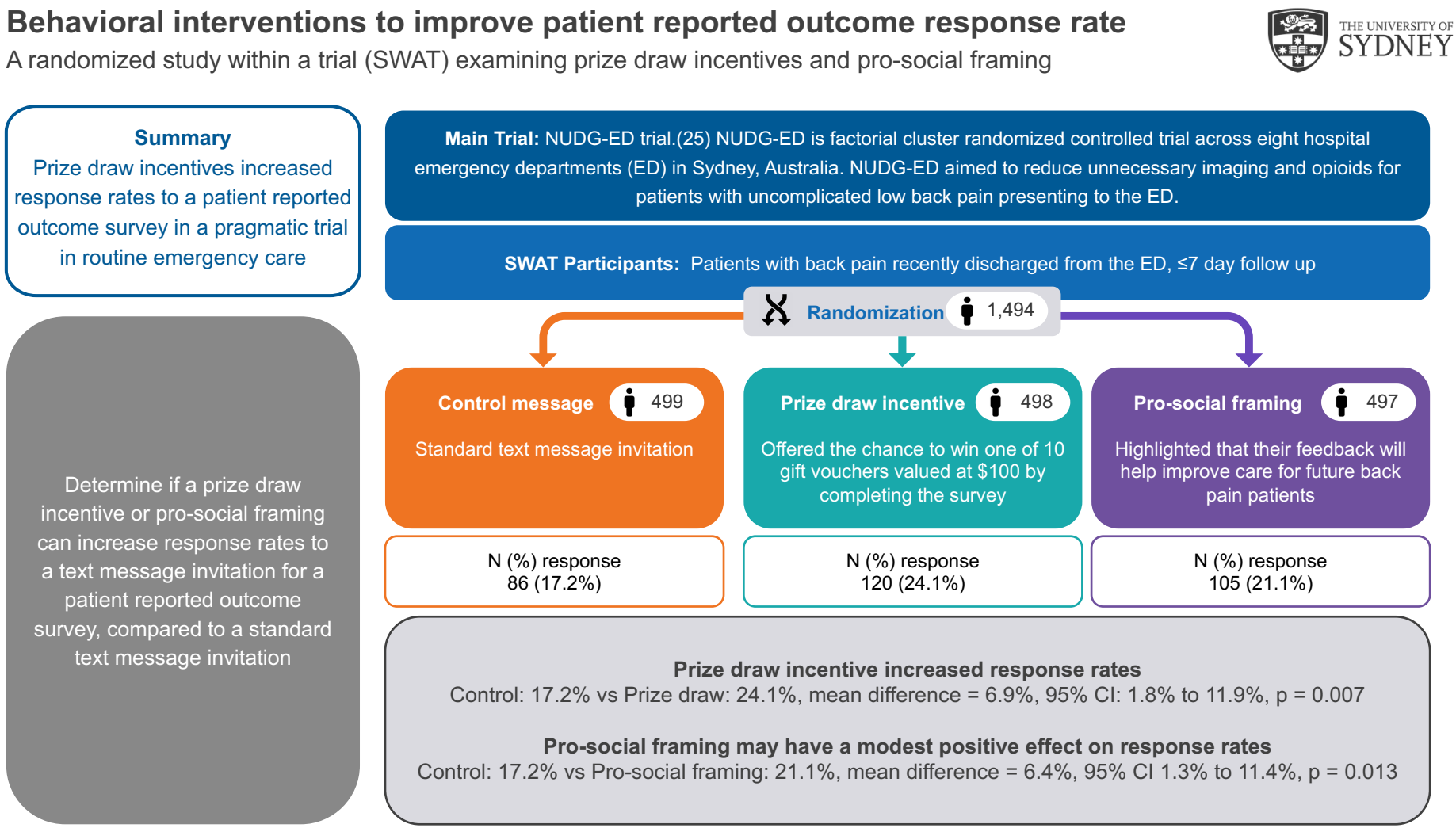
Graphical Abstract



Supplement 1 CONSORT and SWAT reporting guidelines

Section/topic	No	CONSORT 2025 checklist item description	Reported on page no.
Title and abstract			
Title and structured abstract	1a	Identification as a randomised trial	1
	1b	Structured summary of the trial design, methods, results, and conclusions	2
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	6
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	6
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	15
Funding and conflicts of interest	5a	Sources of funding and other support (eg, supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial	15
	5b	Financial and other conflicts of interest of the manuscript authors	15
Introduction			
Background and rationale	6	Scientific background and rationale	4-5
Objectives	7	Specific objectives related to benefits and harms	5
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	15
Trial design	9	Description of trial design including type of trial (eg, parallel group, crossover), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5-9
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	NA
Trial setting	11	Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial was conducted	6
Eligibility criteria	12a	Eligibility criteria for participants	6
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (eg, surgeons, physiotherapists)	NA
Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (eg, intervention manual) can be accessed	6
Outcomes	14	Prespecified primary and secondary outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome	8

Harms	15	How harms were defined and assessed (eg, systematically, non-systematically)	6
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	9
	16b	Explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used	7
	17b	Type of randomisation and details of any restriction (eg, stratification, blocking and block size)	7
			Reported on page no.
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (eg, central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned	7
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	7
Blinding	20a	Who was blinded after assignment to interventions (eg, participants, care providers, outcome assessors, data analysts)	7
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	7
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	8
	21b	Definition of who is included in each analysis (eg, all randomised participants), and in which group	9
	21c	How missing data were handled in the analysis	NA
	21d	Methods for any additional analyses (eg, subgroup and sensitivity analyses), distinguishing prespecified from post hoc	NA
Results			
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome	9 + Figure 1
	22b	For each group, losses and exclusions after randomisation, together with reasons	9
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	9
	23b	If relevant, why the trial ended or was stopped	NA
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (eg, where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended (fidelity))	9
	24b	Concomitant care received during the trial for each group	NA
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	11 + Table 1
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: ● the number of participants included in the analysis ● the number of participants with available data at the outcome time point ● result for each group, and the estimated effect size and its precision (such as 95% confidence interval) ● for binary outcomes, presentation of both absolute and relative effect size	10
Harms	27	All harms or unintended events in each group	NA

Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post hoc	NA
Discussion			
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	13

Citation: Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 Statement: updated guideline for reporting randomised trials. BMJ. 2025; 388:e081123. https://dx.doi.org/10.1136/bmj-2024-081123

*We strongly recommend reading this statement in conjunction with the CONSORT 2025 Explanation and Elaboration and/or the CONSORT 2025 Expanded Checklist for important clarifications on all the items. We also recommend reading relevant CONSORT extensions. See www.consort-spirit.org.

The SWAT reporting guideline

From: Trial Forge Guidance 4: a guideline for reporting the results of randomised Studies Within A Trial (SWATs)

CONSORT 2010 item to be included in publication		Additional information and example text shown in italics where possible	Page
Title and Abstract			
1a	The term 'SWAT' should be used in the title	The SWAT registry number should be included if available: *SWAT [insert number]: [insert title of SWAT]*	1
1b	Structured summary	Structured using these headings: Background, Methods, Results, Conclusion Details of the host trial(s) included in which the SWAT intervention was evaluated	2
1c	Keywords	Include: 'SWAT'; 'Study Within A Trial'; the trial process targeted (e.g. 'recruitment methods'); embedded randomised controlled trial	2
Introduction; Background and objectives			
2a	Scientific background and explanation of rationale for the SWAT	Justify the need for the SWAT; cite systematic review evidence where appropriate Replication SWAT: Also cite previous SWAT evaluations undertaken as part of the rationale	4-5
2b	Specific objectives or hypotheses for the SWAT	State SWAT question as objective *Does [insert SWAT intervention] increase/decrease [outcome] compared to [comparator] in [participants]?*	5

Methods; Trial design			
3a	Description of the SWAT (such as parallel, factorial, cluster), including allocation ratio	Describe the trial design and allocation ratio: *A [insert number of trial arms and trial design] SWAT was undertaken with an allocation ratio of [insert allocation ratio] (intervention detail vs control detail)* State where the SWAT protocol is registered: *The SWAT protocol (number) can be found at [insert details of SWAT repository link]* If SWAT protocol is not registered, include it as an appendix Host trial(s): *The SWAT was embedded in the [insert host trial name(s)]* Reference the host trial's registration number(s) and if the protocol(s) for the host trial is/are available elsewhere or include a link to the study project page(s) Provide a brief description of the host trial(s) using PICO format. At a minimum, age, gender, and ethnicity should be reported per group in addition to any demographics deemed relevant by the host trial team(s); however, we encourage authors to refer to and report in accordance with PROGRESS-PLUS [27] where feasible. If the SWAT was conducted across multiple host trials at the same time, a description of each host trial should be provided *Host trial Participants; Intervention; Comparator; Outcomes*	5
3b	State changes (with reasons) to methods of SWAT following commencement		

		State the ethical approval arrangements for the SWAT: *The SWAT was approved by the Research Ethics Committee [insert name/reference number]* If changes to the SWAT occurred: *The following changes occurred once the SWAT started [insert text]*	
Participants			
4a	State eligibility criteria in SWAT, including differences to those from the host trial(s)	State participant eligibility. This can be tabulated	6
4b	Include setting(s) and location(s) where SWAT data was collected	Describe SWAT data collection methods: *SWAT data were collected in the following settings/locations [insert text] using the following methods [e.g. face to face, postal follow-up, telephone follow-up, electronic data collection]*	6
Interventions			
5	Describe SWAT intervention to enable replication, including how and when interventions were administered and recruitment dates	Briefly describe the SWAT intervention and control. Reference to the SWAT protocol for further details is acceptable if the protocol is available to the reader	7
Outcomes			
6a	State primary and secondary outcome measures for the SWAT	State the primary and outcome measures for the SWAT:	8

	Include how and when they were assessed	*Primary outcome measure: [insert information including how/when/who assessed]* *Secondary outcome measure(s): [insert information including how/when/who assessed]* This information can be tabulated If appropriate: *The following changes occurred once the SWAT started [insert text]*	
6b	Include changes (and reasons) to SWAT outcomes after commencement		
Sample size			
7a	How sample size was determined for the SWAT	SWATs are often individually underpowered due to the sample size being constrained by the host trial(s). A robust estimate of the effect of the SWAT intervention might therefore depend on the aggregation of replicated SWAT evaluations. It is not expected that a formal sample size calculation will always be done *The SWAT sample size depended on the host trial(s) [insert host trial name]; therefore no formal sample size calculation was performed, which is in line with SWAT methodology*. [insert any reasoning for a subsample of the host trial(s) being used – e.g. SWAT was included midway through the trial] State if interim analyses and/or stopping rules were planned or not If interim analyses and/or stopping rules were planned: *The following interim analyses were planned [state analyses here]. The stopping rules were [details here]*	9
7b	When applicable, explanation of any interim analyses and stopping rules for the SWAT		
Randomisation: Sequence generation			

8a	The method used to generate the random allocation sequence for the SWAT	Provide details of the method of randomisation: *Participants were randomised by [insert method with all methodological details]*	7
8b	Type of randomisation; details of any restriction (such as blocking and block size)		
Allocation concealment mechanism			
9	The mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned for the SWAT	Provide details of the method of allocation concealment: *Allocation concealment was achieved by [insert method]*	7
Implementation			
10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions for the SWAT	Provide details of randomisation sequence generation and implementation: *Randomisation was performed by [specify centre or personnel], [specify centre or personnel] enrolled participants and [specify centre or personnel] assigned the participant to the SWAT intervention or comparator*	7
Blinding			
11a	If done, who was blinded after assignment to the SWAT interventions (for example, participants, care providers, those assessing outcomes), and how	Explain who was blinded and if individuals were not blinded note the implications of this: *The [specify stakeholder group, e.g. participants, SWAT team members, outcome assessors, statisticians] were blind and the [specify stakeholder group, e.g. participants, SWAT team members, outcome assessors, statisticians] were not blind to the SWAT intervention.[Note implications of unblinded stakeholders as relevant]*	7
11b	If relevant, a description of the similarity of the SWAT interventions		

Statistical methods			
12a	Statistical methods used to compare groups for primary and secondary outcomes for the SWAT	All analyses for the SWAT should be preplanned, ideally detailed in a SWAT Statistical Analysis Plan (SAP), which might be a short component of the SWAT registry entry. Unless detailed thoroughly and extensively in a publicly available SWAT protocol, the analysis for each outcome should be detailed in the methods of the report. Alternatively, the SAP could be uploaded as supplementary material depending on the journal The analysis section should include the software used, the statistical methods (including significance level for hypothesis testing), and the population used for the analysis (e.g. intention-to-treat or per-protocol)	8
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		
Results			
Participant flow			
13a	For each group, the numbers of participants who were randomly assigned, received intended SWAT intervention, and were analysed for the primary outcome of the SWAT	Provide a participant flow diagram that includes this data Include details of the host trial(s) participants excluded from the SWAT, with reasons, where appropriate	9
13b	For each group participating in the SWAT, losses, and exclusions after randomisation, together with reasons		
Recruitment			
14a	Dates defining the periods of recruitment and follow-up of the SWAT	Detail when SWAT activity took place: *Participant recruitment/follow-up took place between [insert dates]*	9
14b	Why the SWAT ended or was stopped		

		If the SWAT ended or was stopped early: *The SWAT stopped [recruitment/follow up] early due to [insert text]*	
Baseline data			
15	A table showing baseline demographic and clinical characteristics for each group	The context of the host trial(s) for each SWAT evaluation is likely to be different and contextual information about the host trial(s) should be provided In addition to general information about the host trial(s) (see 'Methods'), we suggest a table of participant baseline characteristics for those allocated to each group of the SWAT evaluation if these details are available. At a minimum, age, gender, and ethnicity should be reported per group in addition to any demographics deemed relevant by the host trial team, however, we encourage authors to refer to and report in accordance with PROGRESS-PLUS [27] where feasible	11
Numbers analysed			
16	For each group of the SWAT, the number of participants (denominator) included in each analysis and whether the analysis was by originally assigned groups		10
Outcomes and estimation			
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results should be presented in tables as far as possible rather than only being presented in the body of the text. To facilitate meta-analysis, SWATs should report the actual number of participants in each group in the SWAT evaluation A key element of SWAT evidence is their ability to be replicated. An important principle for reporting research is that new findings should be placed in the context of existing, relevant evidence. Therefore, we recommend, where possible, that an updated meta-analysis be included that presents the results of the current SWAT	11-12
17b	For binary outcomes, the presentation of both absolute and relative effect sizes is recommended		

		combined with previous evaluations of the SWAT intervention. Presentation as a cumulative meta-analysis is particularly helpful because it would help to inform judgements about the need for further evaluations of a SWAT intervention [7]	
17c	Costs associated with the SWAT	Summarise the costs associated with the SWAT: *The total cost of the SWAT was [insert cost], which equates to [insert cost] per participant* Tabulate the additional costs to the trial incurred because of the SWAT, including total cost and cost per participant. This may include direct costs (e.g. printing, postage, animation) and indirect costs (e.g. staff time to prepare mailings). As SWAT evaluations generally need replication, it is useful for trialists to see the costs of both using the SWAT intervention *and* the cost of evaluating the SWAT should they wish to replicate the evaluation If a positive effect (irrespective of statistical significance) was identified, provide a cost per additional participant for whom there is a favourable result (e.g. cost per participant retained). Otherwise, note that cost per participant was not derived	15
Ancillary analyses			
18	Results of any other analyses performed on the SWAT data, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		NA
Harm			
19	All important harm or unintended effects in each group that took part in the SWAT (for	If no harm or unintended effects were collected, this should also be noted	NA

	specific guidance, see CONSORT for harm)		
Discussion			
20	Interpretation consistent with results, balancing benefits and harm, and considering other relevant evidence	Within the discussion, reflect on the population demographics in the context of equality, diversity, and inclusion (e.g. Does the SWAT population reflect the host trial population(s)? If not, why not?)	13
Limitations			
21	SWAT limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses for the SWAT		14
Generalisability			
22	Generalisability (external validity, applicability) of the SWAT findings		15
Implications			
23	Implications for trial practice and SWAT research	These could make use of the cumulative meta-analysis and Trial Forge Guidance 2 [7] on whether further evaluations of the intervention are warranted Consideration should be given to any other replications of the same SWAT and whether the findings are consistent with these or not. In addition, consideration should be given to the populations of other replications of the same SWAT when considering future SWAT research	15
Other information			
24	Registration	Include the information for both the host trial(s) and SWAT	7

	Registration number and name of trial registry	It is recommended that SWATs are registered on a repository to ensure all SWATs performed can be included in the evidence base and support future replication The following repository is available to register SWATs: the Northern Ireland Methodology Hub's SWAT repository (this repository is for SWATs and encourages replications of registered SWATs): https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSWARInformation/Repositories/SWATStore/ SWATs may also be included in the ISRCTN trial registry (https://www.isrctn.com/) and/or the Clinical Trials database (https://clinicaltrials.gov/) as part of the host trial(s)	
25	Protocol Where the full trial protocol can be accessed, if available	Include the information for both the host trial(s) and SWAT	7
26	Funding Sources of funding and other support (such as supply of drugs), role of funders	Include the information for both the host trial(s) and SWAT	16
Additional			
	Data sharing	We suggest authors make the data used to generate their results available as a supplementary file or through data-sharing platforms such as OSF (https://osf.io)	16

Arundel CE, Clark LK, Parker A, Beard D, Coleman E, Cooper C, et al. Trial Forge Guidance 4: a guideline for reporting the results of randomised Studies Within A Trial (SWATs). Trials. 2024;25(1):183.

Appendix Two: Chapter Three metrics

Metrics

The paper presented in Chapter Three was published in the Journal of Physiotherapy which has an impact factor of 9.4 and is a Q1 for Physical Therapy, Sports Therapy and Rehabilitation. The Scimago Journal and Country Rank (2024) is 1.668 and has a H-Index of 95.

Impact

Since publication in July 2024 this paper has been cited six times. The paper was featured in the Journal of Physiotherapy special issue on Behaviour change (Hug, S. and Elkins, M.R., 2025. Behaviour change. Journal of physiotherapy, pp.S1836-9553). It has an Altmetric score of 26 and has been reported in 77 X posts from 49 X users, with an upper bound of 179,811 followers.

Citation

Altinger G, Maher CG, Traeger AC. *Using behavioural economics to improve adherence to home exercise programs* 2024 Journal of Physiotherapy doi: 10.1016/j.jphys.2024.03.003

Appendix Three: Chapter Four metrics and supplementary materials

Metrics

The paper presented in Chapter Four was published in BMJ Quality & Safety which has an impact factor of 6.7 and is a Q1 for Medicine, Health Policy. The Scimago Journal and Country Rank (2024) is 1.997 and has a H-Index of 175.

Impact

Since publication in July 2025 this paper has been cited one time. The paper was awarded the Sydney Health Partners Musculoskeletal Clinical Academic Group Outstanding Publications Award (2025). It has an Altmetric score of 11 and has been reported in 22 X posts from 15 X users, with an upper bound of 130,580 followers.

Citation

Altinger G, Jones C, Ferreira GE, et al. *Effectiveness of clinician-directed default nudges on reducing overuse of tests and treatments in healthcare: a systematic review of randomised controlled trials* 2025 BMJ Quality & Safety doi: 10.1136/bmjqs-2025-018793

Supplementary Material

Table of contents

Supplementary Table 1: PRISMA Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	4
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	4
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	5
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	5
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Supplementary table 2
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	6
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	6
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	5
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources).	6

Altinger G, *et al*. *BMJ Qual Saf* 2025;0:1–14. doi: 10.1136/bmjqs-2025-018793

		Describe any assumptions made about any missing or unclear information.	
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	6
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	6
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	6
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	6-7
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	7
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	6
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	6
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	8
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	14
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	7
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	8
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Supplementary table 3
Study characteristics	17	Cite each included study and present its characteristics.	8 and Table 1
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	10 and Supplementary table 5

Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	7-8 and Table 2 and supplementary table 7
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	7
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	10-12, Figure 2, table 2, Supplementary table 7 and Supplementary figure 1
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	10
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	NA
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	NA
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Supplementary table 7
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	12
	23b	Discuss any limitations of the evidence included in the review.	13
	23c	Discuss any limitations of the review processes used.	13
	23d	Discuss implications of the results for practice, policy, and future research.	13-14
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	4
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	4
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	NA
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	15

Competing interests	26	Declare any competing interests of review authors.	15
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	15

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

Supplementary Table 2: Search strategies

Medline via Ovid

Row 1 Randomised controlled trial

1 randomized controlled trial.pt.

2 controlled clinical trial.pt.

3 randomized.ab.

4 placebo.ab.

5 clinical trials as topic.sh.

6 randomly.ab.

7 trial.ti.

8 1 or 2 or 3 or 4 or 5 or 6 or 7

9 exp animals/ not humans.sh.

10 8 not 9

Row 2 Default nudge intervention

11 (Default* or Default Nudg* or Nudg*).mp.

12 (opt-in* or opt-out*).mp.

13 ((reduc* or chang* or automat* or preselect* or pre-select* or prefill* or pre-fill* or replac* or default* or decreas*) adj3 setting*).mp.

14 ((reduc* or chang* or automat* or preselect* or pre-select* or prefill* or pre-fill* or replac* or default* or decreas*) adj3 (quantity or quantities)).mp.

15 ((reduc* or chang* or automat* or preselect* or pre-select* or prefill* or pre-fill* or replac* or default* or decreas*) adj2 number*).mp.

16 ((reduc* or chang* or automat* or preselect* or pre-select* or prefill* or pre-fill* or replac* or default* or decreas*) adj3 Option*).mp.

17 ((automat* or preselect* or pre-select* or prefill* or pre-fill* or default*) adj2 order).tw.

18 (Status-quo or status quo).mp.

19 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18

Row 3 Outcome of reducing overuse in healthcare

20 ((decreas* or reduc* or chang* or improv* or influenc* or number or Quantity or quantities) adj2 (medicine* or medical or medication*)).mp.

21 ((decreas* or reduc* or chang* or number or quantity or quantities) adj2 Tablets).mp.

22 ((chang* or improv* or influenc*) adj3 decision*).mp.

23 ((decreas* or reduc* or chang* or improv* or influenc*) adj2 number*).mp.

24 ((decreas* or reduc* or chang* or improv* or influenc* or number or quantity or quantities) adj2 Prescri*).mp.

25 ((decreas* or reduc* or influenc* or number or quantity or quantities or unnecessary) adj2 opioid*).mp.

26 ((decreas* or reduc* or chang* or influenc*) adj2 unnecessary).mp.

27 ((decreas* or reduc* or influenc* or number or unnecessary) adj2 (image or imaging)).mp.

28 ((number or unnecessary) adj3 (scan or scans)).mp.

29 ((decreas* or reduc* or number or quantity) adj2 screening).mp.

30 ((improv* or influenc*) adj2 (healthcare or health-care)).mp.

31 ((decreas* or reduc* or chang* or number or quantity or quantities or unnecessary) adj3 test*).mp.

32 ((decreas* or reduc* or number or quantity) adj3 (procedure or procedures)).mp.

33 ((decreas* or reduc* or number or quantity or quantities) adj3 dispens*).mp.

34 ((chang* or improv* or influenc*) adj3 (decision making or decision-making)).mp.

35 ((decreas* or reduc* or chang* or influenc* or number) adj3 (Quantity or quantities)).mp.

36 exp Medical Overuse/

37 (overdiagnos* or over-diagnos* or overtreat* or over-treat* or overus* or over-us* or low value care* or low-value care*).mp.

38 Diagnostic Imaging/

39 Diagnostic Tests, Routine/

40 Inappropriate Prescribing/

41 Inappropriate Prescri*.mp.

42 exp Prescriptions/

43 Analgesics, Opioid/

44 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43

45 10 and 19 and 44

PsychInfo via Ovid

Row 1 Randomised controlled trial

1 "randomized controlled trial".pt.

2 "controlled clinical trial".pt.

3 randomized.ab.

4 placebo.ab.

5 clinical trials as topic.sh.

6 randomly.ab.

7 trial.ti.

8 1 or 2 or 3 or 4 or 5 or 6 or 7

Row 2 Default nudge intervention

36 exp Medical Overuse/

37 (overdiagnos* or over-diagnos* or overtreat* or over-treat* or overus* or over-us* or low value care* or low-value care*).mp.

38 Diagnostic Imaging/

39 Diagnostic Tests, Routine/

40 Inappropriate Prescribing/

41 Inappropriate Prescri*.mp.

42 exp Prescriptions/

43 Analgesics, Opioid/

44 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43

45 10 and 19 and 44

PsychInfo via Ovid

Row 1 Randomised controlled trial

1 "randomized controlled trial".pt.

2 "controlled clinical trial".pt.

3 randomized.ab.

4 placebo.ab.

5 clinical trials as topic.sh.

6 randomly.ab.

7 trial.ti.

8 1 or 2 or 3 or 4 or 5 or 6 or 7

Row 2 Default nudge intervention

26 ((decreas* or reduc* or chang* or influenc*) adj2 unnecessary).mp.

27 ((decreas* or reduc* or influenc* or number or unnecessary) adj2 (image or imaging)).mp.

28 ((number or unnecessary) adj3 (scan or scans)).mp.

29 ((decreas* or reduc* or number or quantity) adj2 screening).mp.

30 ((improv* or influenc*) adj2 (healthcare or health-care)).mp.

31 ((decreas* or reduc* or chang* or number or quantity or quantities or unnecessary) adj3 test*).mp.

32 ((decreas* or reduc* or number or quantity) adj3 (procedure or procedures)).mp.

33 ((decreas* or reduc* or number or quantity or quantities) adj3 dispens*).mp.

34 ((chang* or improv* or influenc*) adj3 (decision making or decision-making)).mp.

35 ((decreas* or reduc* or chang* or influenc* or number) adj3 (Quantity or quantities)).mp.

36 (overdiagnos* or over-diagnos* or overtreat* or over-treat* or overus* or over-us* or "low value care*" or "low-value care*").mp.

37 "Diagnostic Imaging"/

38 "Diagnostic Tests, Routine"/

39 "Inappropriate Prescribing"/

40 "Medical Overuse"/

41 "Inappropriate Prescri*".mp.

42 Prescriptions/

43 "Analgesics, Opioid"/

44 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43

45 10 and 19 and 44

Embase via Ovid

Row 1 Randomised controlled trial

1 randomized controlled trial.pt.

2 controlled clinical trial.pt.

3 randomized.ab.

4 placebo.ab.

5 clinical trials as topic.sh.

6 randomly.ab.

7 trial.ti.

8 1 or 2 or 3 or 4 or 5 or 6 or 7

9 exp animals/ not humans.sh.

10 8 not 9

Row 2 Default nudge intervention

11 (Default* or Default Nudg* or Nudg*).mp.

12 (opt-in* or opt-out*).mp.

13 ((reduc* or chang* or automat* or preselect* or pre-select* or prefill* or pre-fill* or replac* or default* or decreas*) adj3 setting*).mp.

14 ((reduc* or chang* or automat* or preselect* or pre-select* or prefill* or pre-fill* or replac* or default* or decreas*) adj3 (quantity or quantities)).mp.

15 ((reduc* or chang* or automat* or preselect* or pre-select* or prefill* or pre-fill* or replac* or default* or decreas*) adj2 number*).mp.

16 ((reduc* or chang* or automat* or preselect* or pre-select* or prefill* or pre-fill* or replac* or default* or decreas*) adj3 Option*).mp.

17 ((automat* or preselect* or pre-select* or prefill* or pre-fill* or default*) adj2 order).tw.

18 (Status-quo or status quo).mp.

19 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18

Row 3 Outcome of reducing overuse in healthcare

20 ((decreas* or reduc* or chang* or improv* or influenc* or number or Quantity or quantities) adj2 (medicine* or medical or medication*)).mp.

21 ((decreas* or reduc* or chang* or number or quantity or quantities) adj2 Tablets).mp.

22 ((chang* or improv* or influenc*) adj3 decision*).mp.

23 ((decreas* or reduc* or chang* or improv* or influenc*) adj2 number*).mp.

24 ((decreas* or reduc* or chang* or improv* or influenc* or number or quantity or quantities) adj2 Prescri*).mp.

25 ((decreas* or reduc* or influenc* or number or quantity or quantities or unnecessary) adj2 opioid*).mp.

26 ((decreas* or reduc* or chang* or influenc*) adj2 unnecessary).mp.

27 ((decreas* or reduc* or influenc* or number or unnecessary) adj2 (image or imaging)).mp.

28 ((number or unnecessary) adj3 (scan or scans)).mp.

29 ((decreas* or reduc* or number or quantity) adj2 screening).mp.

30 ((improv* or influenc*) adj2 (healthcare or health-care)).mp.

31 ((decreas* or reduc* or chang* or number or quantity or quantities or unnecessary) adj3 test*).mp.

32 ((decreas* or reduc* or number or quantity) adj3 (procedure or procedures)).mp.

33 ((decreas* or reduc* or number or quantity or quantities) adj3 dispens*).mp.

34 ((chang* or improv* or influenc*) adj3 (decision making or decision-making)).mp.

35 ((decreas* or reduc* or chang* or influenc* or number) adj3 (Quantity or quantities)).mp.

36 exp Medical Overuse/

37 (overdiagnos* or over-diagnos* or overtreat* or over-treat* or overus* or over-us* or

S10 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9

Row 2 Default nudge intervention

S11 "(Default* OR "Default Nudg*" OR Nudg*)"

S12 "(opt-in* OR opt-out*)"

S13 (reduc* OR chang* OR automat* OR preselect* OR pre-select* OR prefill* OR pre-fill* OR replac* OR default* OR decreas*) N3 (setting*)

S14 ((reduc* OR chang* OR automat* OR preselect* OR pre-select* OR prefill* OR pre-fill* OR replac* OR default* OR decreas*) N3 (quantity OR quantities))

S15 (reduc* OR chang* OR automat* OR preselect* OR pre-select* OR prefill* OR pre-fill* OR replac* OR default* OR decreas*) N2 (number*)

S16 (reduc* OR chang* OR automat* OR preselect* OR pre-select* OR prefill* OR pre-fill* OR replac* OR default* OR decreas*) N3 (Option*)

S17 (automat* OR preselect* OR pre-select* OR prefill* OR pre-fill* OR default*) N2 ((TI order OR AB order))

S18 (Status-quo OR "status quo")

S19 S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18

Row 3 Outcome of reducing overuse in healthcare

S20 (decreas* OR reduc* OR chang* OR improv* OR influenc* OR number OR Quantity OR quantities) N2 (medicine* OR medical OR medication*)

S21 (decreas* OR reduc* OR chang* OR number OR quantity OR quantities) N2 (Tablets)

S22 (chang* OR improv* OR influenc*) N3 (decision*)

S23 (decreas* OR reduc* OR chang* OR improv* OR influenc*) N2 (number*)

S24 (decreas* OR reduc* OR chang* OR improv* OR influenc* OR number OR quantity OR quantities) N2 (Prescri*)

S25 (decreas* OR reduc* OR influenc* OR number OR quantity OR quantities OR

S40 OR S41 OR S42 OR S43 OR S44 OR S45

S47 S10 AND S19 AND S46

Clinical trials registries

Registries allowed few terms to be searched so searches with the following terms were run.

1 "Default Nudge"

2 "Default" AND "Reduce"

Supplementary Table 3: Studies excluded after full text review

#	Authors	Title	DOI	Reason excluded
1	Adusumalli et al (2023)	Effect of Nudges to Clinicians, Patients, or Both to Increase Statin Prescribing: A Cluster Randomized Clinical Trial.	JAMA cardiology / 2023;8(1):23-30 United States 2023 / DOI: 10.1001/jamacardio.2022.4373	Wrong intervention and outcomes: patient and clinician facing interventions to increase statin prescribing
2	Ahmadi et al (2021)	Protocol for pragmatic randomised trial: integrating electronic health record-based behavioural economic 'nudges' into the electronic health record to reduce preoperative testing for patients undergoing cataract surgery.	BMJ open / 2021;11(11):e049568 England 2021 / DOI: 10.1136/bmjopen-2021-049568	Wrong intervention: multicomponent electronic health system alerts including behaviourally framed messages and opt-out default
3	Altinger and Traeger (2023)	Using behavioural strategies to communicate risks and benefits of medical interventions: insights from the design of a cluster randomised trial in emergency care	BMJ Evidence-Based Medicine / 2023;28(Supplement 1):A28 Netherlands BMJ Publishing Group 2023/ DOI: 10.1136/EBM-2023-POD.57	Wrong intervention: behavioural interventions without a default nudge
4	Ansher et al (2014)	Better medicine by default.	Medical decision making: an international journal of the Society for Medical Decision Making / 2014;34(2):147-58 United States 2014 / DOI:	Wrong study design and outcome: clinical case scenario, interventions aiming to reduce error rates

		10.1177/0272989X13507339	
5 Arnold et al (2020)	Reducing antibiotic prescriptions for urinary tract infection in nursing homes using a complex tailored intervention targeting nursing home staff: Protocol for a cluster randomized controlled trial	JMIR Research Protocols / 2020;9(5):e17710 Canada JMIR Publications Inc. 2020 / DOI: 10.2196/17710	Wrong intervention: diagnostic training, posters and letters
6 Bagga et al (2014)	Better Ventilator Settings Using a Computerized Clinical Tool.	Respiratory Care 08/ 2014;59(8):1172-1177 Irving, Texas American Association for Respiratory Care 2014 08/ DOI: 10.4187/respcare.02223	Wrong study design and intervention: retrospective review of electronic health system decision support tool
7 Baskar et al (2009)	The impact of clinical inertia on default rates in a diabetes clinic	Diabetic Medicine / 2009;26(SUPPL. 1):126-127 Blackwell Publishing Ltd 2009 / DOI: 10.1111/j.1464-5491.2009.02663.x	Wrong study design: observational study
8 Bassa et al (2005)	Impact of a clinical decision support system on the management of patients with hypercholesterolemia in the primary healthcare setting.	Disease Management & Health Outcomes 02/ 2005;13(1):65-72 / Springer Nature 2005 / DOI: 10.2165/00115677-200513010-00007	Wrong study design and intervention: before-after study examining care recommendations through electronic health system alerts

9	Bauer et al (2009)	Efficacy of an algorithm-guided treatment compared with treatments as usual: A randomized, controlled study of inpatients with depression.	Journal of Clinical Psychopharmacology / 2009;29(4):327-333 / US Lippincott Williams & WilkinsUS 2009 / DOI: 10.1097/JCP.0b013e3181ac4839	Wrong intervention and outcomes: Efficacy of an algorithm informed tapering interventions on time to remission
10	Belli et al (2020)	Implementation of a Behavioral Economics Electronic Health Record (BE-EHR) Module to Reduce Overtreatment of Diabetes in Older Adults.	Journal of general internal medicine / 2020;35(11):3254-3261/United States 2020 / DOI: 10.1007/s11606-020-06119-z	Wrong intervention: electronic health system alert involving peer comparison and list prioritisation
11	Belli et al (2023)	Nudges in the electronic health record to promote appropriate diabetes management in older adults - results from a large pragmatic cluster randomized controlled trial	Journal of General Internal Medicine / 2023;38(Supplement 2):S641/ Netherlands Springer New York LLC 2023 / DOI: 10.1007/s11606-023-08226-z	Wrong intervention: electronic health system alert involving peer comparison and list prioritisation
12	Brown et al (2020)	Reducing high-risk geriatric polypharmacy via electronic health record nudges	Journal of General Internal Medicine / 2020;35(SUPPL 1):Netherlands Springer New York LLC 2020 / DOI: 10.1007/s11606-020-05890-3	Wrong intervention: electronic health system commitment or justification alert
13	Broussard et al (2024)	Default Antibiotic Order Durations for Skin and Soft Tissue Infections in Outpatient Pediatrics: A Cluster Randomized Trial	Journal of the Pediatric Infectious Diseases Society, 2024;, piae127, https://doi.org/10.1093/jpids/piae127	Wrong intervention: optional decision support tool

14	Bruyndonckx et al (2018)	The implementation of academic detailing and its effectiveness on appropriate prescribing of pain relief medication: a real-world cluster randomized trial in Belgian general practices.	Implementation science/ 2018;13(1):6 England 2018 / DOI: 10.1186/s13012-017-0703-8	Wrong intervention: clinical practices offered information package
15	Campbell et al (2021)	Multicomponent behavioral intervention to reduce exposure to anticholinergics in primary care older adults.	Journal of the American Geriatrics Society / 2021;69(6):1490-1499/ United States 2021 / DOI: 10.1111/jgs.17121	Wrong intervention: alert encouraging provision of patient information video
16	Courtright et al (2021)	Prognosticating outcomes and nudging decisions with electronic records in the intensive care unit trial protocol	Annals of the American Thoracic Society / 2021;18(2):336-346 United States American Thoracic Society 2021 / DOI: 10.1513/AnnalsATS.202002-088SD	Wrong intervention: accountable justification interventions
17	Crawford et al (2024)	Assessing a behavioural nudge on healthcare leaders' intentions to implement evidence-based practices	PLoS ONE 19(11): e0311442. https://doi.org/10.1371/journal.pone.0311442	Wrong intervention and outcomes: letter to increase access to information
18	Curtin et al (2020)	Deprescribing in Older People Approaching End of Life: A Randomized Controlled Trial Using STOPPFrail Criteria.	Journal of the American Geriatrics Society 04// Malden, Massachusetts Wiley-Blackwell 2020 04// DOI: 10.1111/jgs.16278	Wrong intervention: providing clinicians with a suggested medication withdrawal plan

19	Domino et al (2022)	Nudging primary care providers to expand the opioid use disorder workforce.	Health services research / 2022;57(2):403-410 United States 2022 / DOI: 10.1111/1475-6773.13894	Wrong intervention and outcomes: effect of framing in letters on physician participation in training
20	Fuery et al (2023)	Electronic Health Record Embedded Strategies for Improving Care of Patients With Heart Failure.	Current heart failure reports / 2023;20(4):280-286 United States 2023 / DOI: 10.1007/s11897-023-00614-0	Wrong study design: narrative review
21	Fuller et al (2023)	Awareness with paralysis and symptoms of post-traumatic stress disorder among mechanically ventilated emergency department survivors (ED-AWARENESS-2 Trial): study protocol for a pragmatic, multicenter, stepped wedge cluster randomized trial.	Trials / 2023;24(1):753 England 2023 / DOI: 10.1186/s13063-023-07764-5	Wrong intervention: Multicomponent intervention including default nudge – potentially eligible if effect of default could be isolated. Trial ongoing.
22	Galimam et al (2022)	"Antibiotic hardstop" on electronic prescribing: impact on antimicrobial stewardship initiatives in patients with community acquired pneumonia (CAP) and infective exacerbations of chronic obstructive pulmonary disease (IECOPD).	BMC infectious diseases / 2022;22(1):135 England 2022 / DOI: 10.1186/s12879-022-07117-8	Wrong study design: before-after design
23	Gonzalez et al (2012)	Impact of a managed controlled-opioid prescription monitoring program on care coordination.	The American journal of managed care / 2012;18(9):516-24 / United States	Wrong intervention: notifying clinicians when prescriptions

			2012 / Ref ID: 23009302	filled at multiple pharmacies with recommendations
24	Haward et al (2012)	Default options and neonatal resuscitation decisions.	Journal of medical ethics / 2012;38(12):713-8 England 2012 / DOI: 10.1136/medethics-2011-100182	Wrong study design: vignette study
25	Hempel-Bruder et al (2022)	Combining default choices and an encounter decision aid to improve tobacco cessation in primary care patients: protocol for a cluster-randomized trial.	BMC primary care / 2022;23(1):246 England 2022 / DOI: 10.1186/s12875-022-01859-9	Wrong population and outcomes: patient directed default framing to reduce smoking
26	Kayser et al (2015)	Study of Default Options in Advance Directives	https://clinicaltrials.gov/study/NCT01817686	Wrong outcomes: increasing palliative care discussions
27	Kelley et al (2021)	The protocol of the Application of Economics & Social psychology to improve Opioid Prescribing Safety Trial 1 (AESOPS-1): Electronic health record nudges.	Contemporary clinical trials 2021;103(101242342):106329 United States 2021 / DOI: 10.1016/j.cct.2021.106329	Wrong intervention: electronic health system alert involving accountable justification, commitment and pain tracker conversations
28	Kirkegaard et al (2022)	Evaluating the effectiveness of email-based nudges to reduce postoperative opioid prescribing: study protocol of a randomised controlled trial.	BMJ open / 2022;12(9):e061980 England 2022 / DOI: 10.1136/bmjopen-2022-061980	Wrong intervention: email based intervention with guideline information or peer

				behaviour
29	Kortteisto et al (2014)	Patient-specific computer-based decision support in primary healthcare--a randomized trial.	Implementation Science 01 / 2014;9(1):15-15 BioMed Central 2014 01 / DOI: 10.1186/1748-5908-9-15	Wrong intervention: electronic health system reminders with care suggestions
30	Kraemer et al (2022)	Effect of Different Interventions to Help Primary Care Clinicians Avoid Unsafe Opioid Prescribing in Opioid-Naive Patients With Acute Noncancer Pain: A Cluster Randomized Clinical Trial.	JAMA health forum / 2022;3(7):e222263 United States 2022 / DOI: 10.1001/jamahealthforum.2022.2263	Wrong intervention: peer comparison or justification interventions
31	Kwint et al (2011)	Effects of medication review on drug-related problems in patients using automated drug-dispensing systems: a pragmatic randomized controlled study.	Drugs & aging / 2011;28(4):305-14 New Zealand 2011 / DOI: 10.2165/11586850-000000000-00000	Wrong intervention: results of a medication review sent to community pharmacist for discussion with primary care provider
32	Lauffenburger et al (2021)	Rationale and design of the Novel Uses of adaptive Designs to Guide provider Engagement in Electronic Health Records (NUDGE-EHR) pragmatic adaptive randomized trial: a trial protocol.	Implementation science : IS / 2021;16(1):9 England 2021 / DOI: 10.1186/s13012-020-01078-9	Wrong intervention: multicomponent intervention including default nudge – potentially eligible if effect of default could be isolated. Trial ongoing.

33	Liebschutz et al (2017)	Improving Adherence to Long-term Opioid Therapy Guidelines to Reduce Opioid Misuse in Primary Care: A Cluster-Randomized Clinical Trial.	JAMA Internal Medicine 09 / 2017;177(9):1265-1272 / Chicago, Illinois American Medical Association 09 / DOI: 10.1001/jamainternmed.2017.2468	Wrong intervention: education and decision support website
34	Lillo et al (2022)	A randomized controlled study of biochemical tests in primary care: interventions can reduce the number of tests but usage does not become more appropriate.	Clinical chemistry and laboratory medicine / 2022;60(3):343-350 / Germany 2022 / DOI: 10.1515/cclm-2021-1138	Wrong intervention: multiple interventions including guideline provision, non-interruptive and interruptive alerts with justification
35	Loeb et al (2005)	Effect of a multifaceted intervention on number of antimicrobial prescriptions for suspected urinary tract infections in residents of nursing homes: cluster randomised controlled trial.	BMJ (Clinical research ed.) / 2005;331(7518):669 England 2005 / Ref ID: 16150741	Wrong intervention: multicomponent diagnostic and treatment decision support education and resources
36	Macis et al (2021)	Using Incentives and Nudging to Improve Non-Targeted HIV Testing in Ecuador: A Randomized Trial.	AIDS and behavior / 2021;25(8):2542-2550 United States 2021 / DOI: 10.1007/s10461-021-03215-x	Wrong intervention and outcomes: commitment and incentive intervention to increase HIV testing
37	Mafi et al (2022)	A pragmatic parallel arm randomized-controlled trial of a multi-pronged electronic health record-based clinical decision support tool protocol to reduce low-value	PloS one / 2022;17(12):e0277409 United States 2022 / DOI: 10.1371/journal.pone.0277409	Wrong intervention: electronic health record multi-component alert involving salience of

		antipsychotic prescriptions among older adults with Alzheimer's and related dementias.		information, suggested alternatives and defaults
38	McCabe et al (2022)	The protocol of improving safe antibiotic prescribing in telehealth: A randomized trial.	Contemporary clinical trials / United States 2022 / DOI: 10.1016/j.cct.2022.106834	Wrong intervention: private or public clinician commitments
39	McCarthy et al (2023)	Protocol for a pragmatic stepped wedge cluster randomized clinical trial testing behavioral economic implementation strategies to increase supplemental breast MRI screening among patients with extremely dense breasts.	Implementation science : IS / 2023;18(1):65 England 2023 / DOI: 10.1186/s13012-023-01323-x	Wrong outcomes: patient and clinician directed interventions to increase breast density screening
40	Mestres Gonzalvo et al (2017)	Supporting clinical rules engine in the adjustment of medication (SCREAM): protocol of a multicentre, prospective, randomised study.	BMC geriatrics / 2017;17(1):35 England 2017 / DOI: 10.1186/s12877-017-0426-3	Wrong intervention: decision support intervention
41	Montoy et al (2016)	Patient choice in opt-in, active choice, and opt-out HIV screening: Randomized clinical trial.	BMJ: British Medical Journal / 2016;352(Ai, C., & Norton, E. C. (2003). https://dx.doi.org/10.1016/S0165-1765(03)00032	Wrong population and outcomes: patient directed intervention to increase HIV testing
42	Mudumbi et al (2023)	BE-A-PAL: Behavioral economics and automated analytics to improve palliative care among patients with	JCO Oncology Practice, 19(11_suppl), 268–268. https://doi.org/10.1200/OP.2023.19.11_	Wrong outcomes: increase palliative care discussions

	advanced cancer.	suppl.268	
43 Najafi et al (2019)	Assessment of a Targeted Electronic Health Record Intervention to Reduce Telemetry Duration: A Cluster-Randomized Clinical Trial.	JAMA Internal Medicine / Chicago, Illinois American Medical Association 2019 DOI: 10.1001/jamainternmed.2018.5859	Wrong intervention: electronic health record alert prompting physicians to cancel or renew a telemetry order
44 Oke et al (2024)	Quality improvement project to reduce Medicare 1-day write-offs due to inappropriate admission orders.	BMC health services research / 2024;24(1):204 / England 2024 / DOI: 10.1186/s12913-024-10594-z	Wrong intervention: electronic health record alert reminder
45 Parikh et al (2024)	Researcher at University of Pennsylvania Publishes New Study Findings on Cancer (BE-a-PAL: A cluster-randomized trial of algorithm-based default palliative care referral among patients with advanced cancer)."	Health & Medicine Week, 5 July 2024, p. 5964. Gale General OneFile, link.gale.com/apps/doc/A799593248/ITOF?u=usyd&sid=bookmark-ITOF&xid=92f9c274. Accessed 26 Nov. 2024.	Wrong outcomes: increase palliative care discussions
46 Pate et al (2018)	Effect of an automated patient dashboard using active choice and peer comparison performance feedback to physicians on statin prescribing: The pre-scribe randomized clinical trial	Journal of General Internal Medicine / 2018;33(2 Supplement 1):174-175 Netherlands Springer New York LLC	Wrong intervention and outcomes: patient dashboard with or without peer comparison feedback to increase statin prescribing

47	Picker et al (2017)	A Randomized Trial of Palliative Care Discussions Linked to an Automated Early Warning System Alert.	Critical care medicine / 2017;45(2):234-240 United States 2017 / DOI: 10.1097/CCM.0000000000002068	Wrong intervention and outcomes: early warning alert to increase end of life discussions
48	Rao et al (2021)	Effect of Rapid Respiratory Virus Testing on Antibiotic Prescribing Among Children Presenting to the Emergency Department With Acute Respiratory Illness: A Randomized Clinical Trial.	JAMA Network Open / Chicago, Illinois American Medical Association 2021/ DOI: 10.1001/jamanetworkopen.2021.11836	Wrong intervention: effect of rapid respiratory pathogen tests on antibiotic and care use
49	Richter et al (2023)	The Effects of Opt-out vs Opt-in Tobacco Treatment on Engagement, Cessation, and Costs: A Randomized Clinical Trial	JAMA Internal Medicine / 2023;183(4):331-339 / United States American Medical Association 2023 / DOI: 10.1001/jamainternmed.2022.7170	Wrong population and outcomes: patient directed interventions to reduce smoking
50	Rutten et al (2022)	An Electronic Health Record Integrated Decision Tool and Supportive Interventions to Improve Antibiotic Prescribing for Urinary Tract Infections in Nursing Homes: A Cluster Randomized Controlled Trial.	Journal of the American Medical Directors Association 03// 2022;23(3):387-393 New York, New York Elsevier B.V. 2022 / DOI: 10.1016/j.jamda.2021.11.010	Wrong intervention: electronic health record decision tool with training, pocket cards and information leaflets
51	Soon et al (2019)	Effect of two behavioural 'nudging' interventions on management decisions for low back pain: a randomised vignette-based study in general practitioners.	BMJ Quality & Safety 07// 2019;28(7):547-555 BMJ Publishing Group 2019 07//	Wrong study design: vignette study

		DOI: 10.1136/bmjqs-2018-008659	
52 Smith et al (1996)	An intervention on discharge polypharmacy.	Journal of the American Geriatrics Society / 1996;44(4):416-9 United States 1996 / Ref ID: 8636588	Wrong intervention: computer generated drug list allowing clinicians to cancel, renew or order new prescription for outpatient patients at discharge
53 Tierney et al (1990)	The effect on test ordering of informing physicians of the charges for outpatient diagnostic tests.	The New England journal of medicine / 1990;322(21):1499-504; United States 1990 / Ref ID: 2186274	Wrong intervention: making cost of tests visible to clinicians in order system
54 Vock et al (2022)	PRescribing Interventions for Chronic pain using the Electronic health record (PRINCE): Study protocol.	Contemporary clinical trials 2022;121(101242342):106905 United States 2022 / DOI: 10.1016/j.cct.2022.106905	Wrong intervention: behavioural intervention without default nudge
55 Yadav et al (2018)	A multifaceted intervention to improve prescribing for acute respiratory infection in adults and children in emergency department and urgent care settings (mitigate trial)	Open Forum Infectious Diseases / 2018 Netherlands Oxford University Press 2018 / DOI: 10.1093/ofid/ofy209.103	Wrong intervention: patient and provider education and peer comparison

56	Yadav et al (2019)	A Multifaceted Intervention Improves Prescribing for Acute Respiratory Infection for Adults and Children in Emergency Department and Urgent Care Settings.	Academic emergency medicine: official journal of the Society for Academic Emergency Medicine / United States 2019 / DOI: 10.1111/acem.13690	Wrong intervention: multicomponent intervention including education, peer comparison, commitment and feedback
57	Ye et al (2023)	Structuring healthcare advance directives: Evidence from Chinese end-of-life cancer patients' treatment preferences.	Health expectations: an international journal of public participation in health care and health policy / England 2023 / DOI: 10.1111/hex.13769	Wrong population and outcomes: framing on patient preferences for end-of-life care

Supplementary Table 4: Records included in review

Records	Trials	Record	Author, year	Title
1	1	Main record	Montoy, 2020 (28)	Association of Default Electronic Medical Record Settings With Health Care Professional Patterns of Opioid Prescribing in Emergency Departments: A Randomized Quality Improvement Study.
2	2	Main record	Bachhuber, 2023 (41)	Reducing Opioid Analgesic Prescribing in Dentistry Through Prescribing Defaults: A Cluster-Randomized Controlled Trial.
3	-	Sub record	Bachhuber, 2018 (47)	Reducing the default dispense quantity for new opioid analgesic prescriptions: study protocol for a cluster randomised controlled trial.
4	3	Main record	Bachhuber, 2021(40)	Effect of Changing Electronic Health Record Opioid Analgesic Dispense Quantity Defaults on the Quantity Prescribed: A Cluster Randomized Clinical Trial.
5	4	Main record	Moehring, 2023 (42)	Evaluation of an Opt-Out Protocol for Antibiotic De-Escalation in Patients With Suspected Sepsis: A Multicenter, Randomized, Controlled Trial.
6	-	Sub record	Moehring, 2021 (48)	Effects of an Opt-Out Protocol for Antibiotic De-escalation among Selected Patients with Suspected Sepsis: The DETOURS Trial
7	5	Main record	Poeran, unpublished (29)	An Intuitive, Non-intrusive, Approach to Reduce Patient Harm From Inappropriate Dosing of High-risk Drugs in Older Adult Patients Across an Urban Safety Net Hospital System
8	-	Sub record	Colon Iban, 2023 (45)	Can a Nudge Intervention to Modify Prescribing Of Oxycodone among Elderly Inpatients Decrease Disparities in Prescriptions? Results From A Cluster Randomized Crossover Trial
9	-	Sub record	Colon Iban, 2023 (46)	A Nudge Intervention to Modify Prescribing Of Oxycodone And Gabapentin Among Elderly Inpatients In a Large Safety- Net Hospital System: Heterogeneous Results From A Cluster Randomized Crossover Trial
10	-	Sub record	Jain, 2022 (46)	A Cluster Randomized Crossover Trial to Reduce Inappropriate Dosing of High-Risk Drugs in Hospitalized Elderly Patients: Methodological Considerations
11	6	Main record	Sharma, 2019 (43)	Effect of Introducing a Default Order in the Electronic Medical Record on Unnecessary Daily Imaging during Palliative Radiotherapy for Adults with Cancer: A Stepped-Wedge Cluster Randomized Clinical Trial

Supplementary Table 5 Risk of bias assessment

Study (reference)	Randomisation	Allocation	Baseline Char.	Blinding	Blinding outcomes	Incomplete data	Selective reporting	Analysis
Montoy 2020 (28)	Low	Low	Unclear	High	Low	Low	Unclear	High
Bachhuber 2021 (40)	Low	Low	Low	Low	Low	Low	Low	High
Bachhuber 2023 (41)	Low	Low	Low	High	Low	Low	Low	High
Moehring 2023 (42)	Low	Low	Low	Low	Low	Low	Low	n/a
Poeran unpublished (29)	Unclear	Unclear	Low	Low	Low	Low	High	High
Sharma 2019 (43)	Low	Low	Low	Low	Low	Low	Low	Low

Bachhuber 2023 (41)	Default quantity - 5-tablets	1221	1327	Did not downgrade, narrow confidence interval	n/a, only one comparison did not downgrade per Cochrane	Downgraded one level, due to analysis unadjusted for clustering	Downgraded one level, restricted scope of evidence (limited clinical setting, data from USA only)	n/a only one comparison	**Low**
Bachhuber 2023 (41)	Default quantity - 10-tablets	2010	1327	Did not downgrade, narrow confidence interval	n/a, only one comparison did not downgrade per Cochrane	Downgraded one level, due to analysis unadjusted for clustering	Downgraded one level, restricted scope of evidence (single setting, data from USA only)	n/a only one comparison	**Low**
Moehring 2023 (42)	Opt-out default	384	383	Downgraded one level, confidence interval included potentially meaningful difference and no effect	n/a, only one comparison did not downgrade per Cochrane	Did not downgrade	Downgraded one level, restricted scope of evidence (single setting, highly specific patient population, data from USA only)	n/a only one comparison	**Low**
Poeran (unpublished) (29)	Default dose (combined 8 medications)	1801	1686	Did not downgrade, narrow confidence interval	n/a, only one comparison did not downgrade per Cochrane	Downgraded one level, due to high risk of bias from selective reporting	Downgraded one level, restricted scope of evidence (narrow patient population, data from USA only)	n/a only one comparison	**Low**
Sharma 2019 (43)	Default frequency	679	509	Did not downgrade, narrow confidence interval	n/a, only one comparison did not downgrade per	Did not downgrade	Downgraded one level, restricted scope of evidence	n/a only one comparison	**Moderate**

					Cochrane		(single setting, highly specific patient population, data from USA only)		
Subgroup meta-analysis: reducing overuse of opioids with a 10-tablet default									
Subgroup meta-analysis (28, 40, 41)	Default quantity – 10-tablet default	8793	9393	Downgraded one level, wide confidence intervals including meaningful effect and no effect	Downgraded one level, only 2 of 3 trial had effects in the same direction	Downgraded one level, high risk of bias from analysis	Downgrade one level (overuse in multiple care settings, data from USA only)	n/a too few trials	**Very low**

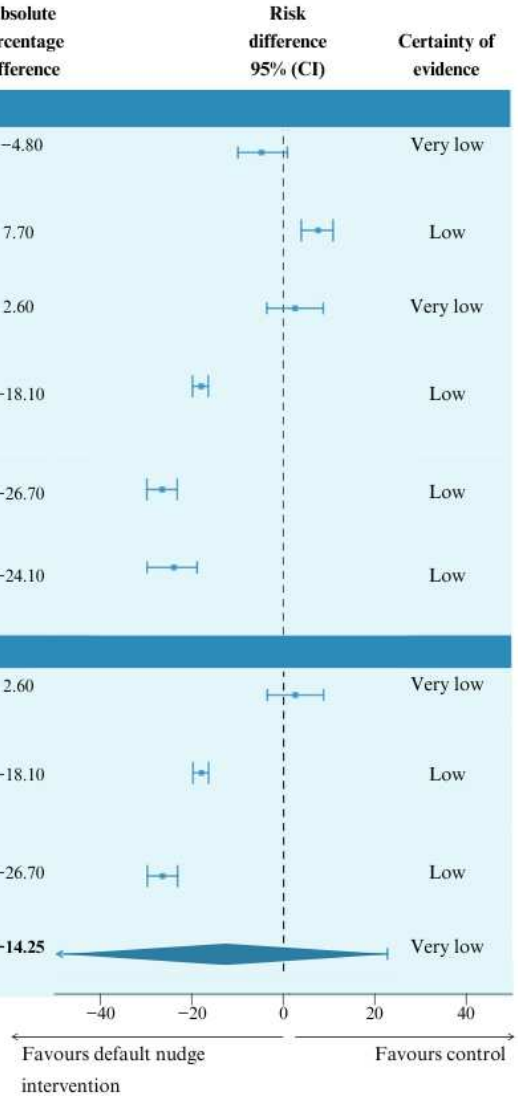
Supplementary Table 7: Standardised synthesis of effect size

Study (reference)	Default nudge	Outcome (Original)	Outcome	N encounters (Control)	N using lower default (Control)	% using lower default (Control)	N Overuse (Control)	% Overuse (Control)	N encounters (Intervention)	N using lower default (Intervention)	% using lower default (Intervention)	N Overuse (Intervention)	% Overuse (Intervention)	Absolute risk difference	95%CI Lower	95%CI Upper
Montoy 2020 (28)	Default quantity – 5 tablets	Prescribing ≤12 tablets	Prescribing >12 tablets	415	217	52.3	198	47.7	1020	582	57.1	438	42.9	-4.8	-10.0	0.9
Montoy 2020 (28)	Default quantity – 10 tablets	Prescribing ≤12 tablets	Prescribing >12 tablets	415	217	52.3	198	47.7	620	308	49.7	312	50.3	2.6	-3.6	8.8
Montoy 2020 (28)	Default quantity – 12 tablets	Prescribing ≤12 tablets	Prescribing >12 tablets	415	217	52.3	198	47.7	969	740	76.4	229	23.6	-24.1	-30.0	-19.0
Bachhuber 2021 (40)	Default quantity – 10 tablets	Prescribing ≤10 tablets	Prescribing >10 tablets	7651	2751	36	4900	64	6163	3337	54.1	2826	45.9	-18.1	-20.0	-16.6
Bachhuber 2023 (41)	Default quantity – 5 tablets	Prescribing ≤10 tablets	Prescribing >10 tablets	1327	548	41.3	779	58.7	1221	410	33.6	811	66.4	7.7	4.0	11.0
Bachhuber 2023 (41)	Default quantity – 10 tablets	Prescribing ≤10 tablets	Prescribing >10 tablets	1327	548	41.3	779	58.7	2010	1367	68	643	32	-26.7	-30.1	-23.4
Moehring 2023 (42)	Opt-out of antibiotic discontinuation	Antibiotics received (non-zero days of therapy) - antibiotic continuation	Continuing antibiotics	384	60	15.6	324	84.4	383	82	21.4	301	78.6	-5.8	-11.0	-0.3
Poeran (unpublished) (29)	All 8 medications	Prescribing default dose	Not prescribing default dose	1801	561	31.2	1240	68.85	1686	564	33.45	1122	66.6	-2.3	-5.4	0.8
Sharma 2019 (43)	Daily imaging	Daily imaging	Daily imaging (imaging during ≥80% of treatments)	679	216	31.8	463	68.2	509	344	67.6	165	32.4	-35.8	-41.0	-30.0

Effect of default quantity nudges on opioid overuse

Study, setting	Intervention group	Control comparison	Outcomes	N (%) Overuse, Control	N (%) Overuse, Intervention	Absolute percentage difference	Risk difference 95% (CI)	Certainty of evidence
All opioid comparisons								
Montoy 2020, Emergency department (28)	5−tablets	Usual care	Prescribing >12 tablets	198/415 (47.7)	438/1020 (42.9)	−4.80		Very low
Bachhuber 2023, Dentistry (41)	5−tablets	Usual care (most commonly null or 30 tablets)	Prescribing >10 tablets	779/1327 (58.7)	811/1221 (66.4)	7.70		Low
Montoy 2020, Emergency department (28)	10−tablets	Usual care	Prescribing >12 tablets	198/415 (47.7)	312/620 (50.3)	2.60		Very low
Bachhuber 2021, Primary care and emergency care (40)	10−tablets	Usual care (most commonly null or 30 tablets)	Prescribing >10 tablets	4900/7651 (64)	2826/6163 (45.9)	−18.10		Low
Bachhuber 2023, Dentistry (41)	10−tablets	Usual care (most commonly null or 30 tablets)	Prescribing >10 tablets	779/1327 (58.7)	643/2010 (32)	−26.70		Low
Montoy 2020, Emergency department (28)	12−tablets	Usual care	Prescribing >12 tablets	198/415 (47.7)	229/969 (23.6)	−24.10		Low
10-tablet default opioid comparison								
Montoy 2020, Emergency department (28)	10−tablets	Usual care	Prescribing >12 tablets	198/415 (47.7)	312/620 (50.3)	2.60		Very low
Bachhuber 2021, Primary care and emergency care (40)	10−tablets	Usual care (most commonly null or 30 tablets)	Prescribing >10 tablets	4900/7651 (64)	2826/6163 (45.9)	−18.10		Low
Bachhuber 2023, Dentistry (41)	10−tablets	Usual care (most commonly null or 30 tablets)	Prescribing >10 tablets	779/1327 (58.7)	643/2010 (32)	−26.70		Low
Pooled estimate*				5877/9393 (62.6)	3781/8793 (43)	**−14.25**		Very low

*Random effects, REML, Hartung–Knapp–Sidik–Jonkman meta-analysis: -14.25 [95%CI -51.4 to 22.9], I2 = 97.0% [94.1%; 98.5%]



Appendix Four: Chapter Five metrics and supplementary material

Metrics

The paper presented in Chapter Five was published in JAMA Network Open which has an impact factor of 13.8 and is a Q1 for Medicine. The Scimago Journal and Country Rank (2024) is 3.546 and has a H-Index of 154.

Impact

Since publication in November 2025 this paper has been cited one time. The paper was awarded the Inaugural Prof Alexandra Barratt Publication Award Wiser Healthcare, NHMRC Centre for Research Excellence Outstanding Publications Award (2025). It has an Altmetric score of 59 and has been reported by 4 news outlets, 2 blogs, 2 Facebook pages, 19 Bluesky posts from 10 Bluesky users, with an upper bound of 19,704 followers, and in 39 X posts from 15 X users, with an upper bound of 52,130 followers.

Citation

Altinger G, Maher CG, Jones CMP, et al. *Multiple Suggested Care Alternatives and Decision-Making of Primary Care Physicians: A Randomized Clinical Trial.* 2025 JAMA Network Open doi:10.1001/jamanetworkopen.2025.42949

Supplemental Online Content

Altinger G, Maher CG, Jones CMP, et al. Multiple suggested care alternatives and decision-making of primary care physicians: a randomized clinical trial. *JAMA Netw Open*. 2025;8(11):e2542949. doi:10.1001/jamanetworkopen.2025.42949

This supplemental material has been provided by the authors to give readers additional information about their work.

eMethods 1. Ethics study materials

Participant invitation

Subject: You are invited to complete a short survey to help us understanding clinical decision making to improve future health system design

You are invited to participate in a 5-minute survey to help us improve future health system design. If you consent you will be randomised into one of two groups. We will then ask you to respond to 2 clinical scenarios that may be commonly seen in primary care, these have no right or wrong answers. Each scenario should take no longer than 1-2 minutes to complete. We will then ask you a few background questions about your location of practice, clinical and teaching experience. Your responses will be confidential and anonymous.

Thank you for contributing to this study.

Adrian Traeger | PhD
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The University of Sydney, Gadigal Country
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Understanding clinical decision making to improve future health system design: a randomised experiment

PARTICIPANT INFORMATION SHEET

Short Title	Understanding clinical decisions
Project Sponsor	University of Sydney, Australia
Coordinating Principal Investigator/ Principal Investigator	Dr Adrian Traeger
Location	Online

1. Introduction

You are invited to take part in a research study looking at better understanding clinical decisions to improve future health system design. You are eligible to participate because you are a primary care physician registered with Qualtrics, practicing in the United States. This study will present participants two clinical scenarios and participants will be asked to select a treatment option.

The study is being conducted within the Institute of Musculoskeletal Health, a partnership between the University of Sydney and The Sydney Local Health District. by Dr Adrian Traeger, Senior Researcher at the University of Sydney, Australia. Ms Gemma Altinger is conducting the study to partially fulfil the requirements of Master of Philosophy at the University of Sydney under the supervision of Dr Traeger.

The study is being sponsored by the University of Sydney, Australia. The study is being supported by a research grant from the Faculty of Medicine and Health, The University of Sydney (CIA Traeger).

This Participant Information Sheet (PIS) will tell you what is involved in the study and help you decide whether or not you wish to take part. Please read this information carefully. If there is anything you do not understand or if you feel you need more information about anything, please ask.

2. Study Procedures

If you agree to participate in this study, you will be asked to sign the Participant Consent Form at the end of this document. You will then be randomised into one of two groups and asked to read two clinical scenarios and answer a single multiple-choice question at the end of each. The two groups will be given different sets of treatment options to choose from. There are no right or wrong answers. You will then be asked to answer 7 simple background questions about your location, years in practice and teaching experience. We expect the survey to take around 5 minutes. If you would like to receive the results of the study, you will have the option to provide your email address at the end – this will be stored in a separate database and cannot be linked to your survey responses. Responses will remain anonymous. You can complete this survey on your phone or computer, in a place convenient to you.

3. Risks

There are no foreseeable risks associated with this study.

4. Benefits

While we intend that this research study furthers health system knowledge and may improve health system design in the future, it will not be of direct benefit to you. However, you will be reimbursed for your time as defined by your membership with Qualtrics.

5. Costs

Aside from giving up your time, we do not expect there to be any costs associated.

6. Voluntary Participation

Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time by closing the online survey. However, only finished surveys will be eligible for financial reimbursement.

Data collected up until the time you withdraw may be included in the study. The study results may be presented at a conference or in a scientific publication. The information you provide for this study will be anonymous. This means that it cannot be re-identified once you have submitted the survey. This means that your information cannot be withdrawn from the study after you submit the survey.

7. Confidentiality

All the information collected from you for the study will be treated confidentially and will be stored on a research database at the University of Sydney. The data will be analysed by the researchers at the University of Sydney. The survey responses will be stored in a study directory on the University of Sydney's server, with access permissible only to the study personnel. A Research Data Management Plan (RDMP) has been created using the Sydney Local Health District RDMP tool. The files will be retained for 10 years from the day the study is completed. Once the retention expires the files will be disposed of. Data will be securely deleted from the RDS once appropriate approval is given by the Records Manager, as specified in the University of Sydney Recordkeeping Manual.

The study results will be used in a higher research degree project. Anonymous data will be stored on an online secure password protected research database accessed within the Institute of Musculoskeletal Health supported by the University of Sydney.

8. Storage of Data

Data will be stored securely within the University of Sydney's Research Data Store (RDS). The RDS is a secure, password protected, web-based, data management tool designed for research purposes. Data stored in the RDS is stored on servers in the University of Sydney data centre. Data is secured and regularly backed-up to protect privacy and confidentiality.

9. Future use of Data

The data collected in this project may also be used in future research studies. The results of this study and non-identified raw data may also be shared in the future with national and international collaborators. If any stored data are used for future research, the research will first be reviewed and approved by an appropriately constituted Ethics Committee.

10. Further Information

When you have read this information, and you have any questions feel free to reach out to Dr Adrian Traeger via Adrian.traeger@sydney.edu.au.

This information sheet is for you to keep.

11. Ethics Approval and Complaints

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 or SLHD-RPAEthics@health.nsw.gov.au and quote protocol number X24-0060.

eTable 1. Scenario 1 – Surgery referral scenario and randomized treatment alternatives presented to control and intervention groups

Clinical Scenario – osteoarthritis The patient is a 67-year-old male, trades person with chronic right hip pain. The diagnosis is osteoarthritis. He has been seeing a physiotherapist and walks daily. You have tried one nonsteroidal anti-inflammatory medication (ibuprofen 600mg three times daily with food) and have stopped them due to lack of efficacy. You decide to refer the patient to an orthopedic surgeon for consideration of hip replacement surgery. The patient agrees to this plan.
Control: Participants given one treatment alternative Before the end of the consultation, however, you check the patients drug history and find that there is a covered nonsteroidal medication that this patient has not tried (see below). What do you do? (please select one) *There is no 'right' answer. Assume there is no difference in financial costs for any option.* a. Refer to orthopedic surgeon and do not start any new medication. b. [Alternative option randomly drawn from below list] [1 alternative will be randomly inserted from the below options: • Refer to orthopedic surgeon and also start indomethacin 25mg two times a day with food. • Refer to orthopedic surgeon and also start Naproxen 500mg twice a day with food. • Refer to orthopedic surgeon and also start diclofenac 50mg two times a day with food.]
Treatment: Participants given two treatment alternatives Before the end of the consultation, however, you check the patients drug history and find that there are 2 covered nonsteroidal medications that this patient has not tried (see below) What do you do? (please select one) *There is no 'right' answer. Assume there is no difference in financial costs for any option.* a. Refer to orthopedic surgeon and do not start any new medication. b. [Alternative option randomly drawn from below list] c. [Alternative option randomly drawn from below list] [2 alternatives will be randomly inserted from the below options: • Refer to orthopedic surgeon and also start indomethacin 25mg two times a day with food. • Refer to orthopedic surgeon and also start naproxen 500mg twice a day with food. • Refer to orthopedic surgeon and also start diclofenac 50mg two times a day with food.]

eTable 2. Scenario 2 – opioid prescribing scenario and randomized treatment alternatives presented to control and intervention groups

Clinical Scenario – opioid prescribing The patient is a 41-year-old male, office worker who you've been seeing to help manage his chronic low back pain for a few months. He has no history of trauma or cancer, attends physiotherapy regularly and enjoys exercise (regular walking, occasional yoga and playing ball games with his kids) when he isn't in pain. Approximately 2 weeks ago he received a prescription for a 3-day supply of oxycodone 5mg, up to twice daily, to help him cope with flare ups, which he says he responded well to. He has presented for a refill of his prescription.
Control: Participants given one treatment alternatives When initiating the order, you receive a pop-up notification on your computer suggesting that you consider an NSAID. What do you do? (please select one) *There is no 'right' answer. Assume there is no difference in financial costs for any option.* a. Continue with prescription for another 3-day supply of oxycodone 5mg up to twice daily. b. [Alternative option randomly drawn from below list]. [1 alternative will be randomly inserted from the below options: • Prescribe indomethacin 25mg two to three times per day with food. • Prescribe diclofenac 50mg two times a day with food. • Prescribe naproxen 500mg two times a day with food. • Prescribe ibuprofen 600mg three times a day with food.]
Intervention subgroup 1: Participants given two treatment alternatives When initiating the order, you receive a pop-up notification on your computer suggesting you consider an NSAID. What do you do? (please select one) *There is no 'right' answer. Assume there is no difference in financial costs for any option.* a. Continue with prescription for another 3-day supply of oxycodone 5mg PO up to twice daily. b. [Alternative option randomly drawn from below list]. c. [Alternative option randomly drawn from below list]. [2 alternatives will be randomly insert from the below options: • Prescribe indomethacin 25mg two to three times per day with food. • Prescribe diclofenac 50mg two times a day with food. • Prescribe naproxen 500mg two times a day with food. • Prescribe ibuprofen 600mg three times a day with food.]
Intervention subgroup 2: Participants given three treatment alternatives When initiating the order, you receive a pop-up notification on your computer suggesting you consider an NSAID. What do you do? (please select one)

There is no 'right' answer. Assume there is no difference in financial costs for any option.

a. Continue with prescription for another 3-day supply of oxycodone 5mg up to twice daily.
b. [Alternative option randomly drawn from below list].
c. [Alternative option randomly drawn from below list].
d. [Alternative option randomly drawn from below list].

[3 alternatives will be randomly insert from the below options:

- Prescribe indomethacin 25mg two to three times per day with food.
- Prescribe diclofenac 50mg two times a day with food.
- Prescribe naproxen 500mg two times a day with food.
- Prescribe ibuprofen 600mg three times a day with food.]

Intervention subgroup 3: Participants given four treatment alternatives

When initiating the order, you receive a pop-up notification on your computer suggesting you consider and NSAID.

What do you do? (please select one)

There is no 'right' answer. Assume there is no difference in financial costs for any option.

a) Continue with prescription for another 3-day supply of oxycodone 5mg up to twice daily.

b) Prescribe indomethacin 25mg two to three times per day with food.

c) Prescribe diclofenac 50mg two times a day with food

d) Prescribe naproxen 500mg two times a day with food

e) Prescribe ibuprofen 600mg three times a day with food.

eMethods 2. GEE model

Primary Analysis: Interaction model with GEE estimation to account for cluster structure

Regression equation:

$$logit(P(Y=1))=\alpha\hat{}+\beta\hat{}1group+\beta\hat{}2S+\beta\hat{}3group*S$$logitPY=1=α^+β^1group+ β^2S+ β^3group∗S

Where
Logit (p(y=1)) = log odds of choosing a high value alternative

$\alpha\ \hat{}\alpha$ ^ = intercept

$\beta\hat{}1\beta$^1 = effect of intervention in scenario 1

$\beta\hat{}2$ β^2 = effect of scenario in control group

$\beta\hat{}3$ β^3 = effect of interaction term (ie the interaction between intervention group and scenario)

Research Protocol

Protocol Number	X24-0060
Study Title	Revisiting medical decision making in situations that offer multiple alternatives: a randomised experiment
Coordinating Principal Investigator	Dr Adrian Traeger, Sydney Local Health District, University of Sydney
Signature: Adrian Traeger	Date: 15.3.24
Co-investigators	N/A.
Student Investigator(s) (if applicable)	Gemma Altinger is conducting the study to partially fulfil the requirements of Master of Philosophy. Gemma will complete the analysis and drafting the results manuscript under the supervision of Adrian Traeger.

Ethics Statement:

The study will be conducted in accordance with the *National Statement on Ethical Conduct in Human Research* (2007) (Link to National Statement) , the *CPMP/ICH Note for Guidance on Good Clinical Practice* (Link to CPMP/ICH) and consistent with the principles that have their origin in the Declaration of Helsinki. Compliance with these standards provides assurance that the rights, safety and well-being of trial participants are respected.

BACKGROUND AND RATIONALE

Unwarranted healthcare variation is the inconsistency of clinical care that is not accounted for by patient symptoms or preferences and is broadly viewed as an indicator of healthcare quality.[1] At the clinician level, variation in medical opinion, lack of awareness of guidelines, uncertainty, and beliefs? have all been proposed to contribute to healthcare variation.[2] Despite efforts to reduce unwarranted healthcare variation through dissemination of guidelines, public awareness campaigns and professional development courses, variations in use of effective care and patient safety are considered significant problems internationally.[2,3]

The influence of cognitive biases could also help explain why unwarranted healthcare variation occurs.[4] Cognitive biases are cognitive processes that can lead to sub-optimal decision making. Despite expert knowledge and judgement, clinicians are not immune to biases that affect decision making and have been associated with guideline-discordant care and diagnostic error.[5-8] For example, status quo bias occurs when a decision maker maintains the current course, the previous decision or the default option, rather than changing course or choosing an alternative option.[9,10] In clinical decision making, status quo bias could look like a clinician prescribing the default quantity of a medication as presented in the electronic health system, rather than reducing or increasing the quantity based on patient need.

Normative economic theory suggests that having more choice increases the decision maker's ability to make a satisfactory decision. Under this assumption the experimental condition that presents two alternatives to the status quo, offers twice the number of reasons to switch from the status quo. However, according to literature on consumer decision-making, the more similar options that are introduced that are equal in attractiveness or trade-off complexity could increase the challenge in calculating the risks and benefits for each option, leading to "choice overload" and suboptimal decisions. A meta-analysis by Chernev et al. (2015) on consumer decision-making found that longer choice lists are more likely to lead to choice overload when the decision is difficult, the choice set is complex, and/or if the decision maker does not have strong prior preferences.[11] Chernev found deferral of choice or reduced choice switching as

strong measures of choice overload, both of which are characteristics of status quo bias. Although none of the studies were conducted on physician decision-making, status quo bias could be a contributing factor to unwarranted healthcare variation: clinical decision making is complex and often involves many treatment alternatives.[12]

Some studies have investigated the influence of the number of treatment alternatives on status quo bias. According to Redelmeier and Shafir (1995), the introduction of an additional care alternative made clinicians significantly more likely to choose the status quo option *(Status quo choice = 53% with 1 alternative vs 72% with 2 alternatives; P<.005)*. These findings failed to replicate in a later study by Roswarski (2006) *(54.5% with 1 alternative vs. 56.0% with 2 alternatives, P = 0.841)*.[13] While the premise of both experiments was sound, both studies are limited regarding external validity and internal validity. Both studies recruited academic physicians and focused on a single scenario which is now clinically out of date. Ideally vignette studies should present more than one scenario to account for within-physician correlations and to optimise external validity.[14]

Suggesting effective treatment alternatives, for example through computer alerts, is one approach to improving care and reducing unwarranted variation.[15] However, if the hypothesis that the number of treatment alternatives provided can increase the likelihood of status quo bias is true, such behavioural interventions could have unintended effects. A pop-up alert suggesting effective alternatives to medicine A (the status quo) could result in clinicians doing more of the status quo. For example, the upcoming NUDG-ED trial (ACTRN12623001000695) aims to reduce the use of opioids for patients with uncomplicated low back pain in the emergency department by using computer alerts that suggest NSAID alternatives. For an intervention like this, knowing if status quo bias can be triggered by introducing more choice alternatives would be useful information for intervention design. If status quo bias is triggered in a controlled survey environment, it is possible that the risk of this cognitive bias increases in real clinical contexts where choice options are larger and involve real risk and patient expectations.[16]

A study by Meeker et. al. (2016) that did involve real clinical decision making found that offering alternatives to inappropriate antibiotic prescribing for acute respiratory tract infections was smaller than expected effects.[17] The decision support alert offered 15 treatment alternatives. It is possible that offering fewer alternatives could have reduced the trade-off complexity and choice overload and led to more decision makers switching from the status quo option.

Alerts in electronic health ordering systems are gaining popularity as a method to improve clinical care. A study looking to identify the number of medical alerts triggered in a 726-bed academic medical center between November 2017 and June 2018 found that 1,625,341 interruptive alerts across 1,474 different categories were triggered.[18] Given the prevalence of medication alerts and decision support systems that are embedded in daily practice, more evidence on the impact of suggesting alternatives and ways of improving these systems is required.

AIMS

Our primary aim is to determine whether primary care physicians are more likely to experience status quo bias in clinical scenarios with multiple treatment alternatives compared with a single treatment alternative. Specifically, we will determine if offering 2 or more treatment alternatives increases the probability of the status quo option being chosen compared to 1 treatment alternative.

METHODS

Study Design

We will conduct a variation of the Redelmeier and Shafir (1995) experiment where we will update the scenario to be more clinically relevant to the current clinical care settings (e.g. medicines used 30 years ago are currently not recommended). We will also add an additional scenario to examine within- and between-clinician variation and increase the external validity of the study.

We will recruit 396 primary care physicians currently in clinical practice in the United States (U.S.). Primary care physicians will be recruited by the company Qualtrics and are blinded to the purpose of the study. As this study is exploring status quo bias anonymity is an important feature of this study design.

198 will be randomly assigned to the control group (one treatment alternative) and 198 to the intervention group (two or more treatment alternatives). Each participant will complete 2 clinical scenarios. Primary care physicians who complete the scenarios and survey will receive $35AUD equivalent compensation for their time. Compensation is administered by Qualtrics, through participants existing membership agreement. After completing the survey participants will have the option to provide their email if they would like to receive the results of the study when complete. This form will be stored separately and cannot be linked to participant survey responses. Participants do not need to provide their email via this survey in order to receive compensation from Qualtrics.

Participants will be randomly assigned to the control and intervention groups. The randomisation schedule will be computer generated by Qualtrics. Allocation will be concealed from participants and investigators. Staff at Qualtrics will be aware of group allocation being responsible for randomisation and data collection, however they are a third party who will not be involved in analysis. All investigators will be blinded to allocation until after analysis is complete.

Participants in the control group will receive 2 clinical scenarios that each include a common presentation in primary care. Within the scenarios a treatment option will be described as the status quo decision (e.g. a previous decision the participant had made or one that is considered the default option). The control group will receive 1 treatment alternative to the status quo.

Participants in the intervention group will receive the same 2 clinical scenarios as the control group, but instead of one treatment alternative they will be given two or more treatment alternatives to choose from. For scenario 2 the intervention group will be further randomised into one of three intervention subgroups. These intervention subgroups will present participants with either two, three or four treatment

alternatives. The order of the scenarios and the treatment alternatives will be randomised to reduce order effects and the influence of prescribing preferences. They will have approximately 2 minutes to complete each scenario and can select one choice only. Data will be collected via Qualtrics online survey.

Study Sites

This study will be coordinated by the Royal Prince Alfred Hospital. Participants of this online experiment will be recruited via Qualtrics. Participants will be eligible primary care physicians in the USA who have identified themselves as wanting to participate in online research. Data will be stored and analysed via the University of Sydney Research Data Store.

SURVEY/QUSTIONNAIRE

STUDY POPULATION

INCLUSION CRITERIA

We will recruit 396 primary care physicians currently in clinical practice in the United States (U.S.) that are enrolled with Qualtrics.

EXCLUSION CRITERIA

Academic physicians or members of the public. Participants that do not consent to partaking in this study.

RECRUITMENT AND CONSENT

Participants will be eligible primary care physicians in the USA who have identified themselves as wanting to participate in online research by enrolling in the Qualtrics participant registry. Primary care physicians will be recruited by the company Qualtrics. Qualtrics will provide 396 completed surveys from primary care physicians. Researchers will have no direct contact with participants.

Participant information will be presented, and consent will be obtained via the Qualitrics survey platform. Once consent is obtained, 198 will be randomly assigned to the control group (one treatment alternative) and 198 to the intervention group (two or more treatment alternatives). Each participant will complete 2 clinical scenarios. Participants who complete the scenarios and survey will receive $35AUD equivalent

compensation for their time. Qualtrics pays participants through their existing membership. Participants will be blinded to the purpose of the study.

Qualtrics are contracted to provide us with 396 completed participant surveys, so there is no risk in not meeting sample size required. Participants and their results will be anonymous collected via a third party so their relationship or any future relationship with researchers and the local health district will not be affected.

DATA COLLECTION

Participants will be randomly assigned to the control and intervention groups. The randomisation schedule will be computer generated by Qualtrics. Allocation will be concealed from participants and investigators. Staff at Qualtrics will be aware of group allocation being responsible for randomisation and data collection, however, will not be involved in analysis. At least 2 investigators will be blinded to allocation until after analysis is complete.

Participants in the control group will receive 2 clinical scenarios that each include a common presentation in primary care. Within the scenarios a treatment option will be described as the status quo decision (e.g. a previous decision the participant had made or one that is considered the default option). The control group will receive 1 treatment alternative to the status quo.

Participants in the intervention group will receive the same 2 clinical scenarios as the control group, but instead of one treatment alternative they will be given two or more treatment alternatives to choose from. For scenario 2 the intervention group will be further randomised into one of three intervention subgroups. These intervention subgroups will present participants with either two, three or four treatment alternatives.

The order of the scenarios and the treatment alternatives will be randomised to reduce order effects and the influence of prescribing preferences. Surveys will be multiple choice questions; no free text will be collected. They will have approximately 2 minutes to complete each scenario and can select one choice only.

DATA ANALYSIS

The primary outcome is the proportion of primary care physicians choosing the status quo option in a choice set. The hypothesis is that exposing participants to 2 or more equivalent treatment choice alternatives in an order set increases the likelihood of choosing the status quo option compared with one treatment alternative.

A generalised linear mixed model will be used to test significance for main effects of exposure to two or more treatment alternatives on the proportion choosing the status quo option, across the two scenarios. For this analysis, the Scenario 2 intervention subgroups will be considered as one group.

Potential effect modifiers

Clinician experience through years of clinical practice and if they supervise medical students will be being collected as potential moderators. Roswarski (2006) found that increased clinician experience and student supervision reduced the likelihood of the status quo option being chosen when a choice set is expanded to include more treatment alternatives.

We will conduct an exploratory subgroup analysis to identify whether any effects of multiple treatment alternatives on status quo bias increases with exposure to 2, 3 or 4 treatment alternatives. A sensitivity analysis will be performed to check if the results were robust to variation in participant attention.

WITHDRAWAL OF CONSENT

Participants can withdraw at any time by closing the online survey. However, only finished surveys will be eligible for financial reimbursement. Data collected up until the time they withdraw may be included in the study. The information you provide for this study will be anonymous. This means that it cannot be

re-identified once participants have submitted the survey, therefore their information cannot be withdrawn from the study after they submit the survey.

DATA STORAGE AND ARCHIVING/RETENTION

Storage:

Data will be stored securely within the University of Sydney's Research Data Store (RDS). The RDS is a secure, password protected, web-based, data management tool designed for research purposes. Data stored in the RDS is stored on servers in the University of Sydney data centre. Data is secured and regularly backed-up to protect privacy and confidentiality. The files will be retained for 10 years from the day the study is completed. Once the retention expires the files will be disposed of. Data will be securely deleted from the RDS once appropriate approval is given by the Records Manager, as specified in the University of Sydney Recordkeeping Manual.

FUTURE USE OF DATA

The data collected in this project may also be used in future research studies. The results of this study and non-identified raw data may also be shared in the future with national and international collaborators. If any stored data are used for future research, the research will first be reviewed and approved by an appropriately constituted Ethics Committee.

RESEARCH DATA MANAGEMENT PLAN (RDMP)

We have completed a research data management plan and attached this to the application in REGIS.

PRIVACY AND CONFIDENTIALITY

All the information collected for the study is anonymous and will be treated confidentially. Data will be stored on a research database at the University of Sydney. Emails collected for distribution of study results will be stored separately and cannot be connected to participant responses. A Research Data Management Plan (RDMP) has been created using the Sydney Local Health District RDMP tool.

ETHICS AND PROTOCOL AMENDMENTS

The conduct of this study will commence once the initial approval process has been completed through Ethics and Governance authorisation at the Royal Prince Alfred.

CONFLICTS OF INTEREST AND MANAGEMENT PLAN

No conflicts of interest have been identified.

PUBLICATION POLICY

AT and GA have both been involved in the conception and design of this study. All authors of the results manuscript will be required to meet the Australian Code for the Responsible Conduct of Research Authorship criteria. Authors will need to make significant intellectual or scholarly contribution to the study and agree to be listed as an author.

Study participants can nominate if they would like to receive a copy of the study results after completing the survey.

STUDY TIMELINE

Task	Start Date	End Date
Ethics Submission	15 March 2024	15 March 2024
Ethics Review and Approval	10 April 2024	11 April 2024
Advertising, recruitment and survey completion	12 April 2024	30 April 2024
Analysis of Data	1 May 2024	1 June 2024
Manuscripts Drafted	2 June 2024	20 June 2024
Submission of Publications and Final Reports	21 June 2024	30 Jun 2024

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Appendix Five: Chapter Six metrics and supplementary materials

Metrics

The protocol presented in Chapter Six was published in BMJ Open which has an impact factor of 2.3 and is a Q1 for Medicine, Health Policy. The Scimago Journal and Country Rank (2024) is 1.016 and has a H-Index of 176.

Impact

Since publication in March 2024 this paper has been cited three times. It has an Altmetric score of 7 and has been reported by 11 X posts from 11 X users, with an upper bound of 18,631 followers.

Citation

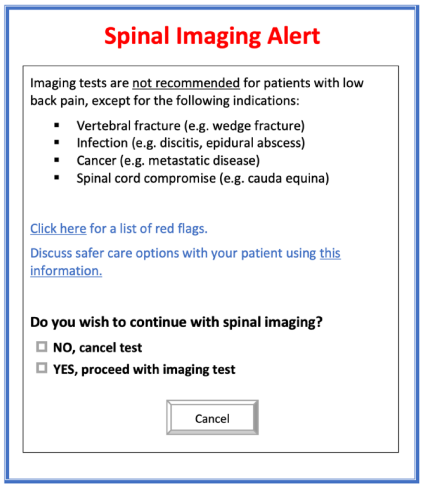
Altinger G, Sharma S, Maher CG, et al. Behavioural 'nudging' interventions to reduce low-value care for low back pain in the emergency department (NUDG-ED): protocol for a 2×2 factorial, before-after, cluster randomised trial, BMJ Open 2024. doi: 10.1136/bmjopen-2023-079870

Supplemental figures 1: Full list of intervention materials

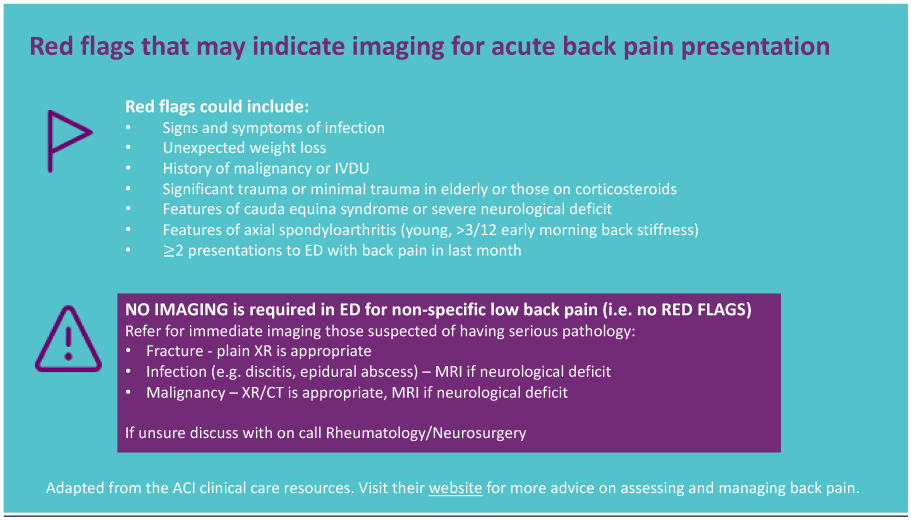
Patient Nudge A: Decision information posters

Patient Nudge B: Decision information brochure

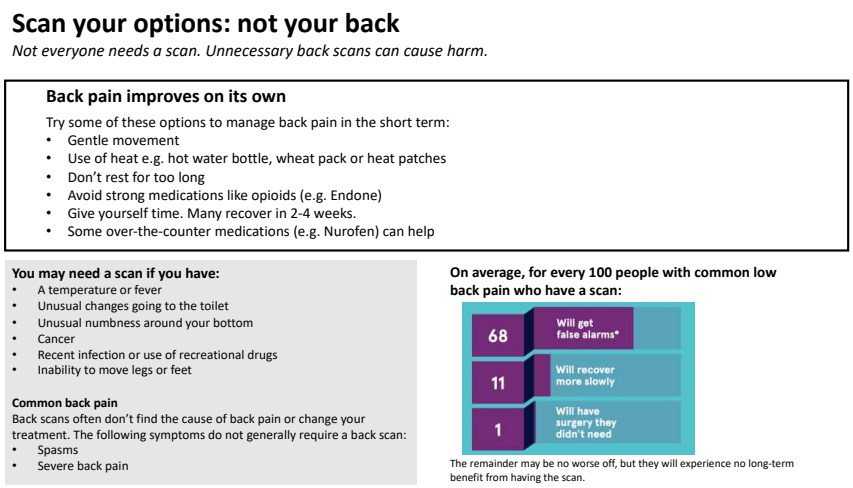
Clinician Nudge A- computer alert when clinicians try to order imaging for low back pain



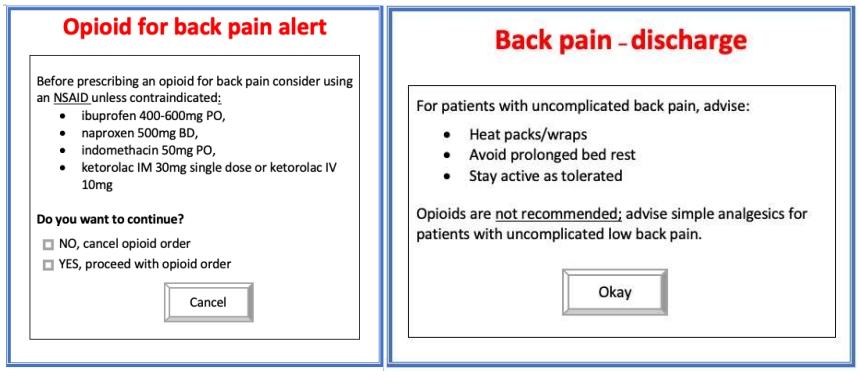
i) List of red flags



ii) Information on safer care options



Clinician Nudge B: computerised alert when clinicians try to administer an opioid medication for back pain



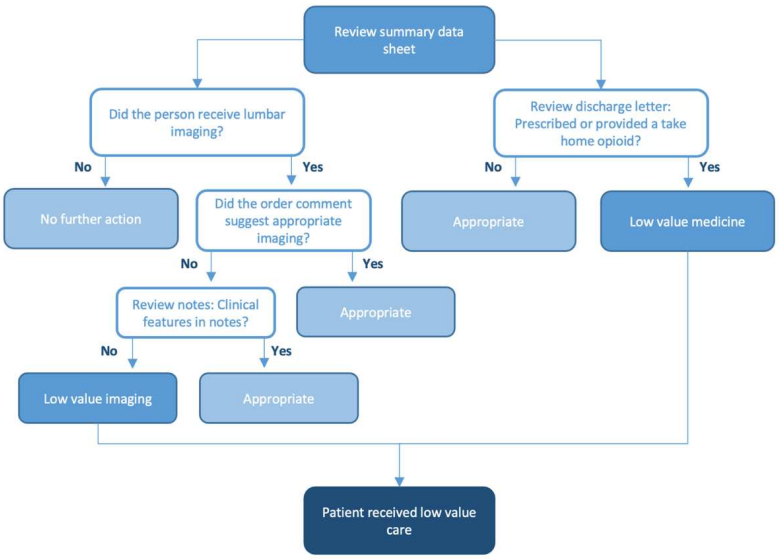
Supplemental table 1: Systematised Nomenclature of Medicine Clinical Terms - Australian Version (SNOMED CT -AU (EDRS)) codes for back pain due to a musculoskeletal condition [61]

DESCRIPTION	CODES
Low back pain with non-specific cause	
Acute low back pain (finding)	278862001
Back pain complicating pregnancy (disorder)	91957002
Backache (finding)	161891005
Blunt injury to back (disorder)	424270008
Chronic back pain (finding)	134407002
Chronic low back pain (finding)	278860009
Coccyx sprain (disorder)	209571002
Complaining of low back pain (finding)	161894002
Degeneration of lumbar intervertebral disc (disorder)	26538006
Displacement of lumbar intervertebral disc without myelopathy (disorder)	20021007
Exacerbation of backache (finding)	135860001
Low back pain (finding)	279039007
Low back strain (disorder)	300956001
Lower back injury (disorder)	282766005
Lumbar spondylosis (disorder)	239880009
Lumbar sprain (disorder)	209565008
Mechanical low back pain (finding)	279040009
Pain in the coccyx (finding)	34789001
Sacral back pain (finding)	61486003
Spasm of back muscles (finding)	203095000
Sprain of ligament of lumbosacral joint (disorder)	209548004
Stiff back (finding)	249921008
Strain of back muscle (disorder)	262965006
Strain of tendon of back (disorder)	262975009
Low back pain with neurological signs and symptoms	
Acute back pain with sciatica (finding)	247366003
Acute sciatica (disorder)	307176005
Chronic sciatica (disorder)	307177001
Injury of lumbar nerve roots (disorder)	24300005
Injury of sciatic nerve (disorder)	86269002
Lumbago with sciatica (finding)	202794004
Lumbago-sciatica due to displacement of lumbar intervertebral disc (disorder)	46960006
Lumbar disc prolapse with radiculopathy (disorder)	202735001
Lumbar radiculopathy (disorder)	128196005
Sciatica (disorder)	23056005
Spinal stenosis of lumbar region (disorder)	18347007
Low back pain due to serious spinal pathology	
Abscess of back (disorder)	309083007
Abscess of back, except buttock (disorder)	19284003
Cauda equina syndrome (disorder)	192970008

Closed fracture lumbar vertebra (disorder)	207957008
Collapse of lumbar vertebra (disorder)	308758008
Compression fracture of lumbar spine (disorder)	426646004
Concussion and edema of lumbar spinal cord (disorder)	212360005
Contusion of back (disorder)	11437003
Contusion of lower back (disorder)	284062002
Crush fracture of lumbar vertebra (disorder)	281933002
Disc prolapse with myelopathy (disorder)	202728009
Discitis (disorder)	2304001
Fracture of coccyx (disorder)	125871005
Fracture of lumbar spine (disorder)	125608002
Fracture of lumbar spine and/or pelvis (disorder)	207986006
Injury of cauda equina (disorder)	230614002
Lumbar disc prolapse with myelopathy (disorder)	202731005
Multiple fractures of lumbar spine and/or pelvis (disorder)	207993005
Open dislocation of coccyx (disorder)	44237008
Open fracture of lumbar vertebra with spinal cord injury (disorder)	48956000
Open fracture of sacrum AND/OR coccyx with spinal cord injury (disorder)	65491009
Traumatic dislocation of joint of lumbar vertebra (disorder)	129166009
Traumatic dislocation of lumbosacral joint (disorder)	129161004

Supplemental figure 2: Guidance on clinical appropriateness of lumbar imaging and opioid prescribing in the ED

Decision tree for appropriateness of lumbar imaging and opioids.



Clinical features indicating urgent lumbar imaging is required

* **Indications for urgent imaging**

Examine clinical notes in eMR for indications for *URGENT imaging, including* :
1. Emergency Department Triage notes
2. Emergency Department Case history

These are:

1) Documented suspicion of any of the following conditions
   - Fracture
   - Cauda equina
   - Infection
   - Malignancy

OR

2) Alerting features for **urgent** imaging in ACP guideline:

- Symptoms or signs of cauda equina syndrome (i.e. new bladder or bowel disturbance, saddle numbness, AND/OR lower motor neuron weakness)
- Symptoms or signs of infection (i.e. new onset of fever and history of intravenous drug use, RECENT spinal procedure, immunosuppression)
- **Major** risk factors for cancer [Hx of Ca that metastasises to bone (e.g., breast, lung, prostate); new onset of low back pain with Hx of Ca, multiple risk factors for cancer]
- **Major** risk factors for vertebral compression # (History of osteoporosis #, systemic long term steroid use, significant trauma, older age (>65 for men, >75 for women) – **multiple** features)

OR

3) Any of the following red flags relevant to Emergency Department setting:
- High-force trauma or minor trauma in older adults (>65 for men, >75 for women)
- >= 2 back pain presentations to Emergency Department in last month

Supplementary file 1: Secondary outcomes-patient survey
A number of patient-reported outcome measures (including patient experience, pain intensity, health related quality of life, reassurance, referral to specialist, intention to seek second opinion and patient beliefs) will be collected in a minimum of 456 patients up to one week after their index ED visit in the 3 month before period and 6 month after period.

- **Patient experience** with emergency care (the 2-items related to 'Overall Assessment of ED Experience' and 2-items from 'Medical Provider' from 36-item Press Ganey ED Survey)[54]:

- **Pain intensity** using Numeric Pain Rating Scale of 0 to 10 with 0 indicating no pain and 10 indicating worst pain imaginable,[55] and disability measured using Henschke et al. 2008 adaptation of item 8 of the SF-36[56]:
    - During the past week, how much did low back pain interfere with your normal work (including both work outside the home and housework?)
      (Not at all, a little bit, moderately, quite a bit, extreme

- **Pain duration** How long have you had your current back pain problem? Tick one (Orebro Musculoskeletal Pain Questionnaire)
    - 0 to 1 week
    - 1 to 2 weeks
    - 3 to 4 weeks
    - 4 to 5 weeks
    - 6 to 8 weeks
    - 9 to 11 weeks
    - 3 to 6 months
    - 6 to 9 months
    - 9 to 12 months
    - Over 1 year

- **Health related quality of life** EQ-5D-5L asks participants to indicate how much trouble they are having in the following:[57]
    - *Mobility*
    - *Self-care*
    - *Usual activities*
    - *Pain/discomfort*
    - *Anxiety/depression*

- **Reassurance** provided using Generic reassurance subscale from consultation-based reassurance[58] asking participants to indicate on a 7-point Likert scale ranging from 'not at all' to 'a great deal':
    - *To what extent did the Doctor:*

- *Tell you that you should not be worried*
- *Tell you that everything would be fine*
- *Reassure you that he/she had no serious concerns about your back*

o *How reassured do you feel that there is no serious condition causing your back pain?*[62]
(On a 7-point Likert scale, ranging from 'not reassured at all' to 'completely reassured')

- **Patient participation in decision-making** (CollaboRATE Tool) (10-point scale from 'No effort was made' to 'Every effort was made')[59]
  - *How much effort was made to help you understand your health issues?*
  - *How much effort was made to listen to the things that matter most to you about your health issues?*
  - *How much effort was made to include what matters to you in choosing what to do next?*

- **Referrals to specialists** provided with a combination of clinical notes review and patient reported diagnosis:
  - *Have you been referred to a specialist for the health condition you went to ED for?*
  - *If yes: Please indicate which specialist the referral was for (drop down menu with a list of specialists)*

- **Intention to seek second opinion** measured using a question from national patient safety foundation, AMA[60]
  - *Thinking about experiences you have had with health care professionals, such as doctors, please tell me how likely or unlikely you are to get a second opinion?*
    (very likely, somewhat likely, not very likely, not at all likely).
  - *Did you see your GP/Physio after attending the ED?*

- **Patient beliefs** about imaging and opioids for low back pain measured on 5-point Likert scale from 'strongly disagree' to 'strongly agree' for the following statements (item 13 and 14 from Jenkins et al. 2015 survey[15] and a new statement on patient beliefs on the effectiveness of opioids).
  - X-rays or scans are necessary to get the best medical care for low back pain
  - Everyone with low back pain should have spine imaging (e.g. X-ray, CT or MRI)
  - [new statement] Opioid medicines are effective long term pain relievers for low back pain

Altinger G, *et al*. *BMJ Open* 2024; 14:e079870. doi: 10.1136/bmjopen-2023-079870

Supplementary file 2: Secondary outcomes-clinician survey

- The survey will be sent to clinicians by the ED Head of Department, and we will obtain consent from clinicians before they complete it. Depending on which group their hospital has been randomised into, clinicians will receive one of the following surveys:

1) Clinician nudge group:
   a) *What is your role in the ED?*
      (Junior Medical Officer, Registrar, Consultant, Career Medical Officer, Nurse, Physiotherapist, other)
   b) *Is it in your scope of responsibility to order imaging for back pain? [If no, then will not receive question g]*
   c) *Is it in your scope of responsibility to provide opioids for back pain? [If no, then will not receive question h] [If no to both b and c, then will not receive question e and f]*
   d) *Were you aware of the NUDG-ED trial being run in your department?*
   e) *How did you find the computerised alerts for back imaging and opioid prescribing?*
      (Very unhelpful, unhelpful, helpful, very helpful)
   f) *How appropriate were the alerts for the patients you saw during the trial?*
      (Mostly inappropriate, sometimes inappropriate, sometimes appropriate, mostly appropriate)
   g) *Did any patient refuse to have imaging when recommended?*
   h) *Did any patient refuse to take opioids when offered for pain relief?*
   i) *Do you have any additional comments or feedback on the trial?*

2) Patient nudge group:
   a) *What is your role in the ED?*
      (Junior Medical Officer, Registrar, Consultant, Career Medical Officer, Nurse, Physiotherapist, other)
   b) *Is it in your scope of responsibility to order imaging for back pain? [If no, then will not receive question f]*
   c) *Is it in your scope of responsibility to provide opioids for back pain? [If no, then will not receive question g]*
   d) *Were you aware of the NUDG-ED trial being run in your department?*
   e) *Did any patient refuse to have imaging when recommended?*
   f) *Did any patient refuse to take opioids when offered for pain relief?*
   g) *Do you have any additional comments or feedback on the trial?*

3) Combined nudge group:
   a) *What is your role in the ED?*
      (Junior Medical Officer, Registrar, Consultant, Career Medical Officer, Nurse, Physiotherapist, other)

b) Is it in your scope of responsibility to order imaging for back pain? [If no, then will not receive question g]

c) Is it in your scope of responsibility to provide opioids for back pain? [If no, then will not receive question h] [If no to both b and c, then will not receive question e and f]

d) Were you aware of the NUDG-ED trial being run in your department?

e) How did you find the computerised alerts for back imaging and opioid prescribing? (Very unhelpful, unhelpful, helpful, very helpful)

j) How appropriate were the alerts for the patients you saw during the trial? (Mostly inappropriate, sometimes inappropriate, sometimes appropriate, mostly appropriate)

f) Did any patient refuse to have imaging when recommended?

g) Did any patient refuse to take opioids when offered for pain relief?

h) Do you have any additional comments or feedback on the trial?

4) Control group:

a) What is your role in the ED? (Junior Medical Officer, Registrar, Consultant, Career Medical Officer, Nurse, Physiotherapist, other)

b) Is it in your scope of responsibility to order imaging for back pain? [If no, then will not receive question d]

c) Is it in your scope of responsibility to provide opioids for back pain? [If no, then will not receive question e]

d) Did any patient refuse to have imaging when recommended?

e) Did any patient refuse to take opioids when offered for pain relief?

f) Do you have any additional comments or feedback on the trial?

Altinger G, *et al*. *BMJ Open* 2024; 14:e079870. doi: 10.1136/bmjopen-2023-079870

Supplementary file 3: Patient participant information and consent forms

Participant Information Statement

Research study to improve emergency department care for low back pain

Thank you for your interest in taking part in research sponsored by the University of Sydney. This sheet tells you about what the study involves and how you can help. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully. Ask questions about things you don't understand or want to know more about by contacting Dr Adrian Traeger 0416 122 784 or adrian.traeger@sydney.edu.au.

What is this study about?

We invite you to take part in a research study about care for low back pain. The results will help us create ways to improve care for low back pain in emergency departments (EDs).

Who can take part in the study?

Adults aged 18 or older who attended ED and who finished their care in the ED can take part. Taking part in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

· Understand what you have read.

· Agree to take part in the research study as outlined below.

· Agree to the use of details about yourself as described.

What does the study involve?

If you agree to take part, we will send you a short online survey. Also, if you agree to be contacted for an interview, a researcher may approach you.

How much of my time will the study take?

If you consent, we will ask you to fill out a brief online survey which will take about 10 minutes. If you consent, you may be invited to attend an interview which will be via Zoom and take about 20 minutes. If you participate in the interview, it will be audio-recorded and transcribed verbatim.

Do I have to be in the study? Can I withdraw from the study once I've started?

Taking part in this study is voluntary. If you do get involved, you can withdraw from the

survey and interview at any time without having to give any reason. Your decision to not take part, will not affect your treatment at the Hospital or relationship with the researchers or university. You are free to stop participating at any stage or refuse to answer any of the questions.

Are there any risks or costs as part of being in the study?

Aside from your time, we do not expect any risks or costs involved with taking part in this study.

Are there any benefits of being part of the study?

By taking part you will be helping important research that might help improve the safety of care for back pain.

What will happen to information about me gathered during the study?

By giving consent, you are willing for us to gather details about you for this research study. We will use your details only for the reasons outlined in this sheet. We will not use it for any other purposes.

We will store details about you confidentially. We will store the de-identified data at the University of Sydney for 15 years, and securely destroy after that. We will publish study findings, but you will not be identifiable. We will keep the details we collect for this study, and we may use them in future projects. By giving your consent you are letting us use the information collected for this study for future projects by the University of Sydney.

Will I receive the results of the study?

You have a right to get the results of this study. You can tell us that you wish to get feedback by ticking the final box on the consent form. The results will be in the form of a one page lay summary of the results. You will get this feedback after the study is finished in 2024.

What do I do next?

When you have read this information, please save this sheet if you wish. Please complete the consent form and the survey. If you agree, you may be contacted to participate in an interview.

Contact

If you have any questions, please feel free to contact Dr Adrian Traeger on 0416 122 784 or adrian.traeger@sydney.edu.au.

What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). HREC of the Southwest Sydney Local Health District (protocol number: XXXX) has approved this study. We have agreed to carry out the study according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect people who agree to take part in research studies. Any person with concerns or complaints about the conduct of this study should contact the Research and Ethics Office and quote project number XXXX:

Research and Ethics Office

Locked Bag 7279, LIVERPOOL BC NSW 1871

02 8738 8304

fax 02 8738 8310

email SWSLHD-Ethics@health.nsw.gov.au,

Website: http://www.swslhd.nsw.gov.au/ethics/default.html

Participant Consent Form

I agree to take part in the research project:

Research study to improve care for low back pain

In giving my consent I acknowledge that:

- I have read the Participant Information Statement and have been given the opportunity to discuss the study and my involvement in it with the researchers.
- The survey and interview, and time involved have been explained to me.
- I understand that participation is voluntary. I am under no obligation to consent.
- I understand that I can withdraw from the survey/interview at any time, without providing a reason and without suffering any penalty. This will not affect treatment at the hospital or my relationship with the researchers or university.
- If I consent, I may be contacted for an interview. If I participate in the interview, it will be audio-recorded and transcribed verbatim. I understand that I can stop my participation at any time.
- I understand that my involvement is strictly confidential and no information about me will be used in any way that reveals my identity.
- I understand that data from this study may be used again for future research purposes, but that all data is strictly confidential and no information about me will be used in any way that reveals my identity.

I consent to being contacted for an interview

- Yes
- No

I consent to participating in the survey

- Yes
- No

- **I would like the researchers to contact me to inform me about the results of the study.**

Supplementary file 4: Clinician participant information and consent forms

Interventions to improve care for low back pain

PARTICIPANT INFORMATION STATEMENT

Thank you for agreeing to be contacted about participating in research sponsored by the University of Sydney. This information sheet tells you about what the study involves and how you can help.

What is this study about?

You are invited to take part in a research study into interventions aimed at reducing unnecessary imaging and opioids for low back pain. The study is led by researchers within the Sydney School of Public Health at the University of Sydney and Emergency Department clinicians.

Investigators on this project are: Dr Adrian Traeger, Dr Sweekriti Sharma, Ms Gemma Altinger, Prof Chris Maher, Prof Kirsten McCaffery, Kirsten Howard, Dr Andrew Coggins and Prof Ian Harris from the University of Sydney; Prof Louise Cullen from University of Queensland; Prof Jeffrey A Linder from Northwestern University, Chicago; Prof Rachelle Buchbinder from Monash University; Prof Enrico Coiera from Macquarie University; Mr Qiang Li from University of New South Wales; Prof Paul Middleton from Liverpool Hospital; A/Prof Naren Gunja from Westmead Hospital. The research is funded by the Australian National Health and Medical Research Council.

Who can take part in the study?

The people eligible to participate in this study are emergency department clinicians such as nurses, physicians (Junior Medical Officer, Registrar, Consultant), and physiotherapists.

Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about. Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.

What does the study involve?

You will be asked to complete a survey about the interventions. Also, if you consent to participate in an interview, you may be approached by a researcher for an interview. All aspects of the study, including results, will be strictly confidential and only the study investigators will have access to the data. A report of the study may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a report.

How much of my time will the study take?

If you consent, you will complete a quick 5-minute survey. If you consent, you may be asked to attend an interview via Zoom for about 20 minutes on one occasion if you agree to participate.

Do I have to be in the study? Can I withdraw from the study once I've started?

Participation in this study is entirely voluntary. You are not obliged to participate in the survey or interview. If you do participate, you can withdraw at any time without having to give any reason and without suffering any penalty. Whatever your decision, it will not affect your relationship with the University of Sydney or the Hospital. Interviews will be audio-recorded and transcribed verbatim. You are free to stop participating at any stage or refuse to answer any of the questions.

Are there any risks or costs associated with being in the study?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

Are there any benefits associated with being in the study?

Your participation in this study may contribute to improved care for back pain in the emergency department.

What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.
Your information will be stored securely, and your identity/information will be kept strictly confidential, except if required by law. We will store the de-identified data at the University of Sydney for 15 years, and securely destroy after that. Study findings may be published and presented at conferences, but you will not be individually identifiable in these publications.

Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the final box on the consent form. This feedback will be in the form of a one page lay summary of the results. You will receive this feedback after the study is finished in 2024.

What do I do next?

When you have read this information, you will be asked to give your consent and complete a short survey. For those who consented to participating in an interview, the study researchers may contact you in the next two weeks to further discuss the study and answer any questions you may have. Not everyone may be required to participate in an interview. We will then arrange a time when it is convenient for you to attend the interview. If you would like to know more at any stage, please feel free to contact Dr Adrian Traeger (Principal investigator) on 8627 6231, adrian.traeger@sydney.edu.au or your head of department.

MASTER Participant Information Statement- Patient. Version 1.0, 05.05.2023

What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the Southwest Sydney Local Health District (protocol number: XXXXXXX). As part of this process, we have agreed to carry out the study according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect people who agree to take part in research studies.

Any person with concerns or complaints about the conduct of this study should contact the Research and Ethics Office and quote project number XXXXXX:

Research and Ethics Office
Locked Bag 7279, LIVERPOOL BC NSW 1871
02 8738 8304
Fax 02 8738 8310
Email SWSLHD-Ethics@health.nsw.gov.au,
Website: http://www.swslhd.nsw.gov.au/ethics/default.html

Participant Consent Form

I agree to take part in the research project:

Research study to improve care for low back pain

In giving my consent I acknowledge that:

- I have read the Participant Information Statement and have been given the opportunity to discuss the study and my involvement in it with the researchers.
- The survey and interview, and time involved have been explained to me.
- I understand that participation is voluntary. I am under no obligation to consent.
- I understand that I can withdraw from the survey/interview at any time, without providing a reason and without suffering any penalty. This will not affect treatment at the hospital or my relationship with the researchers or university.
- If I consent, I may be contacted for an interview. If I participate in the interview, it will be audio-recorded and transcribed verbatim. I understand that I can stop my participation at any time.
- I understand that my involvement is strictly confidential and no information about me will be used in any way that reveals my identity.
- I understand that data from this study may be used again for future research purposes, but that all data is strictly confidential and no information about me will be used in any way that reveals my identity.

I consent to being contacted for an interview

- o Yes
- o No

I consent to participating in the survey

- o Yes
- o No

- o I would like the researchers to contact me to inform me about the results of the study.

MASTER Participant Information Statement- Patient. Version 1.0, 05.05.2023

Appendix Six: Chapter Seven metrics and supplementary materials

Metrics

The paper presented in Chapter Seven was published in Canadian Medical Association Journal which has an impact factor of 12.2 and is a Q1 for Medicine. The Scimago Journal and Country Rank (2024) is 0.915 and has a H-Index of 216.

Impact

Since publication in April 2026 this paper has an Altmetric score of 17 and has been reported by 42 X posts from 23 X users, with an upper bound of 253,748 followers.

Citation

Altinger G, Sharma S, Maher CG et al, *Behavioural nudges to reduce low-value care for low back pain in the emergency department (NUDG-ED): a 2 × 2 factorial, pragmatic cluster randomized trial.* CMAJ 2026 doi: 10.1503/cmaj.251595

Supplemental Online Content

Appendix 1, as submitted by the authors. Appendix to: Altinger G, Sharma S, Maher CG, et al. Behavioural nudges to reduce low-value care for low back pain in the emergency department (NUDG-ED): a 2 × 2 factorial, pragmatic cluster randomized trial. *CMAJ* 2026. doi: 10.1503/cmaj.251595.

Supplement 1: Ethics approved trial protocol

NUDG-ED: Trial of behavioural 'nudging' interventions to reduce low-value care for low back pain in the Emergency Department. Trial Protocol

Sponsor
The University of Sydney

Coordinating Principal Investigator:
Name: Dr Adrian Traeger
Position: Senior Research Fellow
Institution: Institute for Musculoskeletal Health, School of Public Health, The University of Sydney and Royal Prince Alfred Hospital
Responsibilities: Drafting the research protocol, procurement of funding and management of funding, ethics application oversight, overall responsibility for the project, recruitment, supervision, liaison with emergency department staff, conducting interviews, analysis and write-up of the research project.

Lead Investigator:
Name: Ms Gemma Altinger
Position: PhD Student
Institution: Institute for Musculoskeletal Health, School of Public Health, The University of Sydney and Royal Prince Alfred Hospital
Responsibilities: Drafting the research protocol, ethics application, overall responsibility for the project, recruitment, liaison with emergency department staff, consumer involvement activities, conducting interviews, analysis and write-up of the research project

Lead Investigator:
Name: Dr Sweekriti Sharma
Position: Research Fellow
Institution: Institute for Musculoskeletal Health, School of Public Health, The University of Sydney and Royal Prince Alfred Hospital
Responsibilities: Drafting the research protocol, ethics application, overall responsibility for the project, recruitment, liaison with emergency department staff, conducting interviews, analysis and write-up of the research project

Lead Investigator:
Name: Professor Chris Maher
Position: Director
Institution: Institute for Musculoskeletal Health, School of Public Health, The University of Sydney and Royal Prince Alfred Hospital
Responsibilities: Contribute to research protocol, overall responsibility for the project, supervision, liaison with emergency department staff, analysis and write-up of the research project

Principal Investigator
Name: Prof Paul Middleton
Position: Director
Institution: South Western Emergency Research Institute, Liverpool Hospital
Responsibilities: Contribute to research protocol, overall responsibility for the site, liaison with emergency department staff, analysis and write-up of the research project

Principal Investigator
Name: Dr Jeremy Lawrence

Appendix 1, as submitted by the authors. Appendix to: Altinger G, Sharma S, Maher CG, et al. Behavioural nudges to reduce low-value care for low back pain in the emergency department (NUDG-ED): a 2 × 2 factorial, pragmatic cluster randomized trial. *CMAJ* 2026. doi: 10.1503/cmaj.251595.

Position: Director of Emergency Medicine
Institution: Fairfield Hospital
Responsibilities: Contribute to research protocol, overall responsibility for the site, liaison with emergency department staff, analysis and write-up of the research project

Principal Investigator
Name: Adjunt Professor Kevin Pile
Position: Senior Rheumatologist
Institution: Campbelltown Hospital
Responsibilities: Contribute to research protocol, overall responsibility for the site, liaison with emergency department staff, analysis and write-up of the research project

Principal Investigator
Name: Dr Matthew Smith
Position: Director of Emergency Medicine
Institution: Bankstown Lidcome Hospital
Responsibilities: Contribute to research protocol, overall responsibility for the site, liaison with emergency department staff, analysis and write-up of the research project

Principal Investigator
Name: Dr James Mallows
Position: Director of Emergency Medicine Research
Institution: Nepean Hospital
Responsibilities: Contribute to research protocol, overall responsibility for the site, liaison with emergency department staff, analysis and write-up of the research project

Principal Investigator
Name: Dr Richard McNulty
Position: Emergency Staff Specialist
Institution: Blacktown and Mt Druitt Hospitals
Responsibilities: Contribute to research protocol, overall responsibility for the site, liaison with emergency department staff, analysis and write-up of the research project

Principal Investigator
Name: A/Prof Naren Gunja
Position: Emergency Physician and Toxicologist
Institution: Westmead Hospital
Responsibilities: Contribute to research protocol, overall responsibility for the site, liaison with emergency department staff, analysis and write-up of the research project

Associate Investigator
Name: Dr Ahilan Parameswaran
Position: Emergency Physician
Institution: Bankstown Hospital Emergency Department
Responsibilities: Contribute to research protocol, overall responsibility for the site, liaison with emergency department staff, analysis and write-up of the research project

Associate Investigator
Name: Mr Qiang Li
Position: Senior Biostatistician
Institution: The George Institute, University of New South Wales
Responsibilities: Contribute to research protocol, contribute to sample size calculation, plan statistical analysis, and analysis of data

Associate Investigator
Name: Dr Richard Cracknell
Position: Director, Emergency Department
Institution: Campbelltown and Camden Hospitals
Responsibilities: Contribute to research protocol, overall responsibility for the site, liaison with emergency department staff, analysis and write-up of the research project

Associate Investigator
Name: Dr Mark Salter
Position: Emergency Physician
Institution: Nepean Hospital
Responsibilities: Contribute to research protocol, overall responsibility for the site, liaison with emergency department staff, analysis and write-up of the research project

Associate Investigator
Name: A/Prof Andrew Coggins
Position: Senior Emergency and Trauma Attending Staff Specialist
Institution: Westmead Hospital
Responsibilities: Contribute to research protocol, overall responsibility for the site, liaison with emergency department staff, analysis and write-up of the research project

1. SUMMARY

Study Title	NUDG-ED: Trial of behavioural 'nudging' interventions to reduce low-value care for low back pain in the Emergency Department
Aims/Objectives	Primary aim is to determine the effectiveness of a patient nudge, clinician nudges, or both, on low-value care for low back pain in the ED. We define low-value care as an encounter where any opioid was administered or where an imaging test that was not clinically indicated was provided. Secondary aims are to determine if the interventions lead to non-inferior short-term patient-reported outcomes (satisfaction with care, worry, pain, function, quality of life) and superior clinician-reported outcomes (knowledge of evidence-based care, beliefs) and cost-effectiveness compared with standard care. We also aim to evaluate process measures and unintended consequences (representation rate, readmission rate, opioid use in non-musculoskeletal pain).
Study design	A 2x2 factorial, open label, before-after, cluster randomised controlled trial design
Planned sample size	2416 encounters for back pain due to a musculoskeletal condition across 8 sites, over 9 months (ie, 302 encounters per site)
Inclusion criteria	Clinician participants: ED clinicians who manage back pain. Patient participants: patients 18 years or over presenting to ED with low back pain diagnosed with back pain due to a musculoskeletal condition.
Study procedures	We will randomly allocate hospital sites to receive i)no intervention, ii) patient nudges, iii) clinician nudges, or iv) patient and clinician nudges. ***Patient nudges*** Patient nudges will include 6 digital decision information posters displayed on 55-inch LCD screens and a decision information brochure which patients can access using their smartphone (via the QR code on the digital posters) or a paper version that will be stocked in a brochure holder attached to the LCD screen ***Clinician nudges*** eMR will display an alert when physician attempts to prescribe an opioid or imaging test and when patients with low back pain are being discharged. The interventions will run for 6 months following a 3 month period where all sites are in the control group. Outcomes will be collected from the eMR and through case note reviews.
Analysis considerations	To detect an effect of either the patient nudges or the clinician nudges, on low-value care, with an effect size of 10% and with 80% power, alpha set at 0.05, and assuming an intra-class correlation coefficient of 0.10, and an intra-period correlation of 0.09, we require 2416 encounters due to a musculoskeletal condition across 8 sites, over 9 month period (ie, 302 encounters per site, over 3 month baseline and 6 month intervention period).
Study duration	The expected duration of this study is 9 months, starting at receipt of ethical approval.

2. BACKGROUND AND RATIONALE

There is increasing global recognition that use of low-value care – healthcare services that are ineffective or offer little patient benefit – is a pervasive problem.[1] An Australian systematic review identified 156 low-value health services listed on the Medical Benefits Schedule (MBS), that were either ineffective or unsafe.[2] Examples included routine diagnostic imaging for low back pain, knee arthroscopy, and several types of spinal surgery.[2] These services can have negative consequences for the patient, clinician and the health system. In recognition of the impact on quality and safety of care and resource stewardship, reducing low-value care has become an international priority, motivating awareness campaigns across 25 countries.[3]

Low back pain is the leading cause of disability worldwide,[4] is the 5th most common reason to visit the ED,[5] and is often associated with low-value care.[6] Our recent analysis of 6393 back pain presentations to ED found 23.6% received lumbar imaging and 69.6% received opioids.[7] Neither of these services is recommended for management of uncomplicated low back pain because of their poor benefit-to-harm profile. Low-value lumbar imaging has immediate harms, such as exposure to radiation, increased wait times,[8] and increased length of stay.[9] Long term harms of imaging include the detection of irrelevant findings (e.g. 'degenerative discs') that correlate poorly with symptoms, increase patient concern, and trigger use of costly, ineffective procedures such as spinal surgery.[10] Similarly, harms from opioids are well documented. In the short-term opioids can cause nausea, vomiting, constipation and dizziness. Long-term harms include dependence, overdose and death. Opioids also have surprisingly little evidence of benefit for acute low back pain,[11, 12] yet it remains a common reason for their prescription.[13] Between 2007-2016 the number of Australians dying or hospitalised from poisoning by prescription opioids increased by 38% and 62% respectively.[14]

The drivers of low value care are well documented. Although clinicians are highly trained and provided with clinical protocols and guidelines, every clinical decision occurs in a complex health system. Poor care can therefore be viewed as a system problem.[15, 16] proposed drivers of poor clinical care to include i) money and finance; 2) knowledge, bias, and uncertainty; and 3) power hierarchies and human relationships. In the public sector, where money and finance may have less influence on care decisions, low value care is likely driven by the latter two categories. For example, in Emergency Care settings, clinicians may provide a non-indicated imaging test because they cannot recall the clinical guidelines (knowledge), out of habit or clinical inertia (cognitive bias), or because they are uncertain about the likelihood of serious pathology (uncertainty).[17] Emergency Department clinicians facing substantial time pressure may choose to administer opioids for low back pain to facilitate clinical assessment, manage patient expectations, or reduce the likelihood of representation (uncertainty, human relationships). This suggests that education and training alone is unlikely to prevent low value care.

There is limited evidence on the effectiveness of strategies to reduce use of low value imaging and opioids for low back pain. A 2015 systematic review and earlier Cochrane review concluded there was an absence of effective strategies to reduce low-value imaging.[18, 19] Similarly, a 2020 systematic review of opioid stewardship interventions showed that although several strategies have been implemented (e.g. education, hospital policies, electronic medical record (eMR) changes, registries) there was a lack of high quality randomised controlled trials to determine whether these strategies work.[20] Recently an intervention to reduce low-value care for low back pain was tested in a high quality RCT in 4491 patients attending ED.[21] The intervention, which focused on resource-intensive clinician education and feedback, reduced opioid initiation, but it did not change imaging rates.

Past interventions may have been ineffective because they ignored some of the behavioural factors that influence human decision making. Decision making, including clinical decision making, can be influenced by context, heuristics, and social and cognitive biases.[22, 23] A recent systematic review of 21 qualitative studies, including 209 health care professionals and 330 patients, highlighted the importance of considering the barriers and enablers to de-implementation when designing interventions.[24] In the context of opioid deprescribing they found that some key barriers included pressures on prescribers (i.e., time constraints, emotional toll on prescribers, prescriber knowledge and preconceptions, and ineffective healthcare systems), limited opioids alternatives, and reluctance to change. Enablers included clear communication, expectation setting and highlighting the negative effects of opioids and the benefits of deprescribing.[24] Behavioural economics has demonstrated that in many decision making contexts humans may rely on particular heuristics, or rules of thumb, to make decisions. These heuristics can be helpful and do not always lead to poorer decision making.

However, in some contexts these heuristics can lead to biases, systematic errors or suboptimal decision making. A systematic review of 213 studies found that nineteen types of heuristics and biases were present in patients and clinicians medical decision making.[25] Seventy three studies looked specifically at clinicians with 68% (n=145) finding a bias or heuristic present in their clinical decision making.[25]

The effect of heuristics and biases can help explain the persistence of low-value care despite clinician education and awareness campaigns.[22, 23] These heuristics and biases can be leveraged through the use of 'nudges' in order to improve decision making. 'Nudges' are changes to the way choices are presented or structured that can alter behaviour without restricting or prohibiting options.[26] Nudges can be a light-touch, low-cost, scalable way to change behaviour.

A recent systematic review[27] included 42 RCTs using clinician nudges to address low-value care across all health areas. This review found that across the use of nudges that leveraged social norms, defaults, reminders, and increasing the visibility of consequences, 86% of them were effective at improving clinician decision making. In a randomised study of 120 physicians,[28] physicians prescribed fewer opioids and imaging tests when the computer screen was structured with alternatives to imaging and opioids (e.g. patient education, reassurance, simple analgesics) being listed prominently as default options.[28] These nudges make decision-relevant information readily accessible and highlight the preferred decision. This is thought to reduce the cognitive load and supports clinicians to make better clinical decisions - making sure patients get the tests and treatments they need, and not those they don't. Despite promising effects, such light-touch clinician nudges have been under-researched in ED.

Importantly, however, clinician nudges may be ineffective if patients request imaging[29] or opioids.[30] Behavioural economists argue that one of the reasons people make decisions that can harm them in the future is because of *present bias*.[31, 32] Present bias refers to when people value immediate benefits or harms, over the longer term benefits or harms. This could mean that patients may have difficulty balancing the perceived benefits and harms of imaging and opioids. For instance, the harms of an opioid may be perceived as being in the distant future, but the perceived benefits are seen to be immediate, so clinicians and patients prioritise the immediate benefits even if the future harms are substantial.

Decision information is a category of nudging that supports decision makers by simplifying complex information, highlighting decision consequences, and providing a social reference point.[33] Our research has shown that a patient nudge providing decision information in waiting rooms, framed in terms of the lack of immediate benefits as well as describing the harms of imaging, reduced patient's intention to request imaging.[34, 35] However, no randomised controlled trial has investigated whether patient- and clinician- nudges, alone or in combination, can reduce the use of low-value care in the ED.

3. STUDY AIMS

Primary aim

To determine the effectiveness of patient nudges, clinician nudges, or both interventions compared with no intervention on low-value care (non-indicated imaging test, opioid at discharge, or both) for people with low back pain that is due to a musculoskeletal condition, in the ED.

Secondary aims

The secondary aims of this study are:

- To determine if the interventions lead to non-inferior short-term patient-reported outcomes (satisfaction with care, worry, pain, function, quality of life) compared with standard care.
- To calculate the cost-effectiveness of the intervention.
- To evaluate process measures (patient beliefs, patient reassurance, clinician engagement with computer alerts, perceived helpfulness of the computer alerts), and unintended consequences (representation rate, readmission rate, opioid use for non-musculoskeletal pain).
- To describe patient and clinician experiences of the interventions.

4. PARTICIPATING SITES

The participating hospitals are located across three Local Health Districts in Sydney (Western Sydney Local Health District, Nepean Blue Mountains Local Health District, Southwest Sydney Local Health District).

5. STUDY DESIGN

NUDG-ED is a 2x2 factorial, open label, before-after, cluster randomised controlled trial design (Figure 1). This involves randomising clusters–in our case eight hospital Eds–to one of four groups after a 3-month period where all sites are in the control group.

We used SPIRIT checklist to report the protocol.[36]

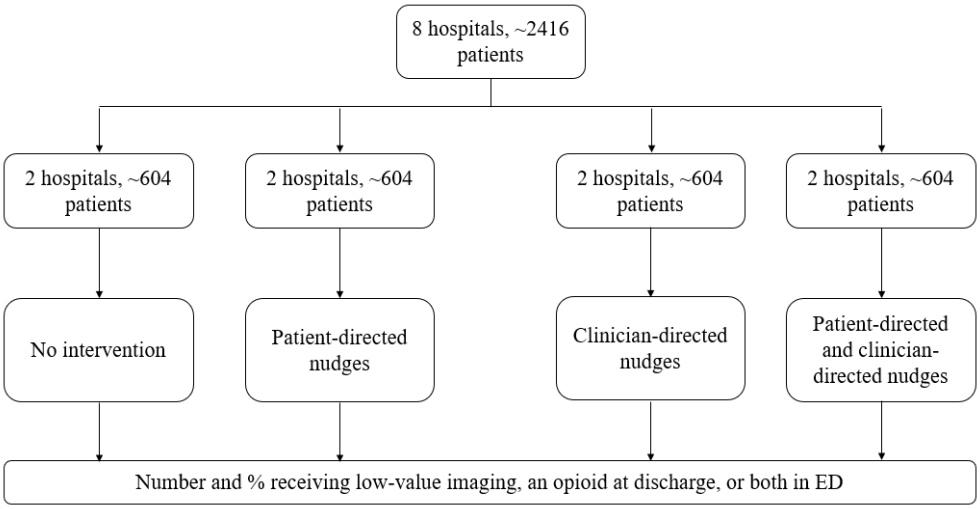


Figure 1: 2x2 factorial, open label, before-after, cluster randomised controlled trial design

5.1 Expected Study Duration

The expected duration of this study is 9 months, starting at receipt of ethical approval.

5.2 Data Sources and Population

Clinician participants

Clinician participants will be ED staff at study sites who are involved in the care of patients presenting to ED with a primary complaint of low back pain. This includes physicians (Junior Medical Officer, Registrar, Consultant), nurses, and physiotherapists.

For study sites allocated to both intervention and no-intervention group, ED clinical directors will notify staff of the trial including aims, site allocation, and the nature of the interventions. This support email is considered part of the intervention. For study sites allocated to 'no intervention' that receive no nudges, practice will continue as usual. After the intervention period, ED Directors will invite participating ED clinicians to complete a survey and subset to participate in semi-structured interviews.

Patient participants

Patient participants will be 18 years or over, presenting with low back pain and diagnosed with back pain due to a musculoskeletal condition. We will invite a random sub-sample of patients who present to ED with low back pain (identified through eMR review) during the study, to participate in a follow-up period. To confirm eligibility, clinician investigators will use the eMR to identify people with back pain using a list of Systematized Nomenclature of Medicine (SNOMED) diagnostic codes that correspond with musculoskeletal conditions (Appendix 1). We will exclude patients who were diagnosed with a non-musculoskeletal condition e.g. renal colic.

We plan to contact potential patient participants via text message, using the software program Twilio. The message will include an invitation to participate and a link to complete an online survey. All potential participants will be notified of the study via a hospital recruitment poster shown on a 55-inch advertising screen located in the waiting room, and a recruitment poster attached to the end of the decision information brochure.

Box 1. Nested study of recruitment methods

Background
Low back pain is under-researched in ED.[37, 38] In particular, studies of patient-reported outcomes and experiences following an ED visit are rare. This could be due in part to difficulty recruiting study participants. Identifying methods to enhance recruitment, such as the format of a text message invitation, could optimise research in ED.[38] Different formats of messages have been used to increase response rates. A systematic review showed that a monetary incentive doubled the chance of participants completing or partially completing a mailed questionnaire.[39] Similarly, messages using an appeal to social good had significantly higher response rate in a mailed survey compared with a standard letter. It is unclear whether these approaches lead to a better response rate when study invitations are sent via a text-message to people attending the ED.

Aim
To determine whether the language and format of text-message invitations can influence the response rate for an ED survey.

Methods
An experimental study nested within a randomised controlled trial. NSW Health staff (ED directors) will send one of three, randomly selected versions of a text message invitation to ~2416 patients. Participants will be randomised to receive either 'Message A', or 'Message B', or 'Message C'. The text message intervention will read as follows:

Message A [control]

Dear [PATIENT_NAME],
We hope you are going well after your recent visit to our Emergency Department. We are interested in what you thought of our care and whether you noticed some aspects of ED waiting area. Our voluntary survey will take only 5 minutes to complete. This survey is part of a voluntary study and is being conducted by myself and Dr Adrian Traeger from the Uni of Sydney. To opt out reply NO -- to begin the survey, visit [LINK TO SURVEY]
Kind regards
Dr XX, Director, XX Hospital ED

Message B [Appeal to social good]

Dear [PATIENT_NAME],
We hope you are going well after your recent visit to our Emergency Department. We are interested in what you thought of our care and whether you noticed some aspects of ED waiting area. Our voluntary survey will take only 5 minutes to complete. ***The results will develop better ways to help people with back pain in the ED.*** *This survey is part of a voluntary study and is being conducted by myself and Dr Adrian Traeger from the Uni of Sydney. To opt out reply NO -- to begin the survey, visit [LINK TO SURVEY]*
Kind regards
Dr XX, Director, XX Hospital ED

Message C [Incentive]

Dear [PATIENT_NAME],
We hope you are going well after your recent visit to our Emergency Department. We are interested in what you thought of our care and whether you noticed some aspects of ED waiting area. Our voluntary survey will take only 5 minutes to complete. This survey is part of a voluntary study and is being conducted by myself and Dr Adrian Traeger from the Uni of Sydney.

Appendix 1, as submitted by the authors. Appendix to: Altinger G, Sharma S, Maher CG, et al. Behavioural nudges to reduce low-value care for low back pain in the emergency department (NUDG-ED): a 2 × 2 factorial, pragmatic cluster randomized trial. *CMAJ* 2026. doi: 10.1503/cmaj.251595.

Everyone who completes the survey will automatically go into a lucky draw to win one of 10 Myer vouchers valued at $100*
To opt out reply NO -- to begin the survey, visit [LINK TO SURVEY]
Kind regards
Dr XX, Director, XX Hospital ED

Outcome
The proportion of patients responding to the survey in those who received 'Message A' vs 'Message B' vs 'Message C'.

Sample size
Our previous text-message based study[35] suggests a 33% response rate. To detect a difference in response rate of 7% (33% in the control group and 40% in any of the intervention groups), with 80% power and alpha set at 0.05, we would require a minimum of 767 patients with low back pain discharged from ED in each group (total n= 2301).

Analysis
Descriptive analyses will be done to report the response rate for all participants in three groups. We will calculate the number and proportion of participants responding to messages and will be grouped by age, sex, ethnicity and socioeconomic status.

Ethical issues
Consent
We are seeking a waiver of consent for patient participants for the nested study because it is impractical and because obtaining consent would create a greater burden to patients than the intervention itself.[40] However, patient will be notified that they may be contacted by the ED via posters in the waiting room screen, a physical flyer provided to patients presenting with back pain by clerical staff at each site, and a recruitment poster attached to the end of the decision information brochure.

Monetary incentives
Fair distribution of benefits and risks of research is one of the key principles of ethical research.[41] Participants invest their time to participate in research deserve some benefit in return.[41] We will provide this in the form of a ticket to a lucky draw to win one of 10 Myer vouchers valued at $100.

It is appropriate to provide such incentive to participants in research projects that are not risk rated as high risk, such as this project.[42] We will maintain the anonymity of responses, while having a mechanism to send participants the incentive and enter them into the draw at the same time. For this we will separate the data collection and the incentive mechanism by entering the data from the completed instrument and the incentive entry in completely separate tables without any relational link between the two tables.[42]

In running the lucky draw, we will comply with the NSW lottery laws and draws will be administered and conducted by someone independent of the research team.[42]

5.3 Consent process
Consent procedures for clinician participants
To ensure a robust comparison between the newly implemented nudge interventions and 'usual' care, we are seeking a waiver of consent for ED clinician participants under the NHMRC National Statement on Ethical Conduct in Human Research 2007 (updated 2018) clause 2.3.10.[40] Below we describe our justification:

i) Involvement in the research carries no more than low risk to participants
Involvement in the trial does not expose clinician participants to any additional risk or discomfort than a standard activity that is regularly undertaken at the ED. The eMR nudge intervention does not adversely affect the rights and welfare of patients as the clinicians will be free to deliver care as they believe appropriate. Clinicians regularly receive similar changes to the eMR interface to reduce low-

value healthcare without being notified or asked for consent (e.g., WSLHD has implemented eMR alerts to reduce inappropriate drug level tests since 2016).

ii) The benefits from the research justify any risks of harm associated with not seeking consent

Risk of harm to clinician participants in this trial is negligible. The benefits of this research, on the other hand, will include new evidence on interventions to support ED clinicians in their decision-making for people presenting with back pain, and better outcomes for health services and patients.

Potential harm associated with not seeking consent:

- Potential for frustration at being "studied" without consent; however, we believe this risk to be very low, as eMR alerts and quality improvement initiatives are routinely implemented in ED practice.
- Potential for frustration from receiving a text message from the health service, among those who do not see the recruitment notice in the ED waiting area (either because they did not see it, had limited health literacy or because of language barriers)

By contrast, the benefits of this trial will include:

- Evidence on interventions to support decisions about diagnostic imaging and opioids by ED clinicians, for patients with back pain. Effective interventions could substantially reduce (unintended) harm to patients
- Evidence on interventions to reduce patient anxiety
- Evidence on interventions to reduce patient exposure to unnecessary radiation and risk of opioid dependence

iii) It is impractical to obtain consent

Obtaining consent would create a greater burden to clinicians than the intervention itself. It is impractical (in both time and money) to obtain the consent of all ED clinicians eligible to participate in this trial across 8 sites. Further, obtaining consent from clinician participants in the 'no intervention' group would disclose the existence of the trial to them, which may affect their behaviour and provision of 'usual' care in the control group, preventing the aim of the trial being achieved.

iv) There is no known or likely reason for thinking that participants would not have consented if they had been asked

We have no reason to believe that ED clinicians would not consent to participating in the trial. Outcomes are based on routinely collected data in aggregate and use of unnecessary care cannot be attributed to individual clinicians. Many ED clinicians may find the intervention/s useful as they encourage guideline-concordant care and care that improves patient outcomes.

v) There is sufficient protection of privacy

Data are only accessible to PIs and a statistician who have appropriate approvals. All information will be presented as high-level, aggregate summaries and no personal information will be disclosed.

In our previous trial to reduce musculoskeletal diagnostic imaging by high requesting Australian general practitioners (Bond University HREC application ID: LA03323, published in JAMA[43, 44]), we were granted a waiver of consent based on similar reasons to those outlined above. The trial involved sending a feedback letters to GPs with their diagnostic imaging request rate compared to their peers and compared this to no intervention.

Clinician participation in process analysis

We will seek consent from a subset of clinicians to participate in semi-structured interviews after the intervention period. We will recruit ~40 clinicians (depending on information adequacy)[45] who were exposed to the eMR nudge intervention: physicians and allied health/nursing staff of different professional levels. After the intervention period, the ED Director at each site will invite clinician participants to participate in a semi-structured interview via email messages along with the participant information statement and consent form. Clinicians willing to participate will complete the eConsent form.

Consent procedures for patient participants

All patients who attend one of the 4 ED sites allocated to the patient nudges during the study period will be exposed to the intervention and enrolled in the study. We are seeking a waiver of consent to include patient participants in the trial and collect their health service outcomes because: i) the intervention to change waiting room communications carries no more than low risk to patients; ii) the benefits of this research outweigh the risks; and iii) it is impractical to obtain consent and more burdensome than the study itself. See Figure 8 for a summary of our consent procedures and where we believe a waiver of consent is needed.

To assess our primary outcome, for each eligible encounter clinician researchers will examine imaging requests, ED discharge letters, ED imaging reports and hospital admission reports using a standardised reporting survey. This will be done remotely by approved clinician reviewers using the eHealth platform from NSW Health using their Stafflink ID and password to login to the eMR. These data will remain in the health service and will not be stored, only read by approved clinician researchers for coding purposes. Clinician researchers will complete a standardised chart review form to review the notes and those data will be stored in REDCap (see attachment 'Standardised Chart Review Form'). We are seeking a waiver of consent to collect these data because it is impractical and obtaining consent would create a greater burden to patients than the data collection process itself.[40] Please refer to section 5.7 and Figure 8 for more details. We have this reliable method to code the clinical notes of people presenting to ED with back pain, before.[46]

We also plan to collect patient reported outcomes from a subset of 456 patient participants in the trial. To obtain consent to collect these outcomes from patients, ED directors will send people presenting with back pain during the study period a text message study invitation via the automated platform Twilio within seven days of completing their treatment in the ED, using the mobile number and first name provided at ED check-in. Each potential participant will be given 2 reminder text messages to complete the survey. All potential participants will be notified of the survey, the potential to be text messaged about the voluntary survey, and an opportunity to opt out via a poster shown on the 55" waiting room screen, and a recruitment poster attached to the end of the decision information brochure. (Appendix 2).

For the process evaluation we will conduct semi-structured interviews in a subset of patient participants to explore reactions to the waiting room cues. We will recruit ~40 patients (precise sample size will be determined by information adequacy, ie, when interviews no longer generate new information to answer our research question)[45] who attended the ED. Participants willing to be contacted for an interview will give their consent at the same time as consenting for the survey. Those who consent to be contacted may receive a call from a researcher who will explain the study to the participants, obtain informed consent, and conduct the interviews over video conference. Interviews will be recorded and transcribed. We will conduct interviews over the phone for those who are willing to participate but do not use Zoom.

In the nested randomised recruitment study (Box 1) we plan to investigate the routine ways of contacting patients attending ED to complete patient reported outcome measures/patient reported experience measures after their visit. The primary outcome of this nested study is the response rate. It is impractical to ask for consent for people to participate in the nested study and there is negligible risk of harm, therefore we are asking for a waiver of consent. For more information on consent for the nested recruitment study, please see Figure 8.

5.4 Study Procedure

Control period

Our control period will be the first 3 months before the intervention period when all the sites are receiving no intervention. We will collect data throughout the control period on the primary outcome and our patient-reported experience measures. During the control period all sites will receive standard care.

Intervention period

We will randomly allocate the 8 hospitals (clusters) into one of four groups: i) no intervention; ii) patient nudges; iii) clinician nudges; iv) patient nudges and clinician nudges for six months after the control period.

Patient nudges: Making decision information salient

Patient nudges will include 6 digital decision information posters displayed on 55-inch LCD screens (Patient Nudge A – Figure 2) and a decision information brochure (Patient Nudge B – Figure 3) which patients can access using their smartphone (via the QR code on the digital posters) or a paper version that will be stocked in a brochure holder attached to the LCD screen.

Figure 2: Patient Nudge A- Example of a decision information poster targeting opioids for back pain. These digital posters will be displayed on LCD screens, these will also include QR codes linking to Patient Nudge B, the decision information brochure (full list of intervention materials included in Appendix 1)

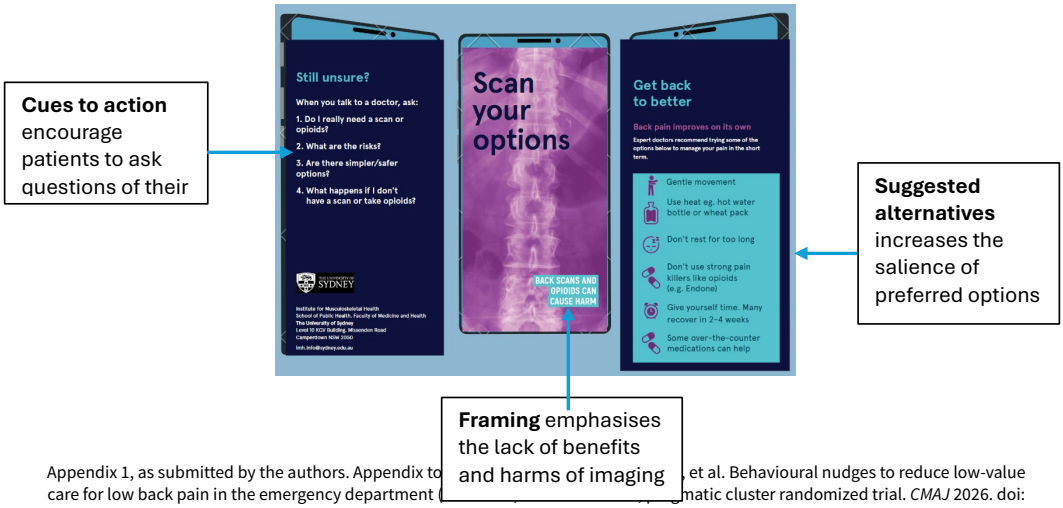


Figure 3: Patient Nudge B- Example of smartphone-based decision information brochure. Patients will have access to this information via a QR code or printed decision information brochures.

Theory and evidence behind the patient nudges

These patient information materials are behaviourally informed, utilising several behavioural science techniques. The patient nudges are *making decision information visible* for patients in the ED waiting room. They provide simplified information that is directly relevant to immediate next steps for patients with low-back pain. The information is provided at a time just before they will be making care decisions with their clinician to be more readily available in their memory. The *salience* of this information is increased by presenting the relevant messages on attractive, attention-grabbing posters that are presented on a large, prominently placed LCD screens in the ED waiting room.[33]

Framing effects highlight when decision makers preferences and judgements are influenced by how decision information is described or framed.[26] Framing can be used to shift the decision maker's perspective of the choice elements and consequences.[47] For example, two hospital field experiments to increase handwashing found that framing hand hygiene in terms of benefits to the health of the patients was more effective than framing in hand hygiene in terms of benefits to the health of the doctors.[47] Framing techniques can leverage our understanding of present bias to improve decision making by focusing on immediate harms (or lack of benefits) rather than longer-term harms. Both patient nudges will frame the decision consequences in terms of the lack of benefits and the potential harms of imaging and opioids (Figure 2). Messages such as "Opioids Don't Help Back Pain" and "Back Scans Rarely Find the Cause of Pain" aim to frame imaging and opioids in terms of their lack of benefit. Messages such as "Scan Your Options, Not Your Back," aim to frame imaging and opioids in terms of their potential harms such as overdiagnosis and addiction (Figure 3).

Setting clear expectations has been identified as an enabler for deprescribing interventions.[24] As such, one of the decision information posters will focus on clearly communicating and setting expectations that opioids will not be prescribed upon discharge (Figure 2).

Messenger effects can influence how people receive information. Some studies on social influence have shown that not only the content of messages is important in influencing behaviour, but also the choice of messenger.[48] This could be the authority, trustworthiness, relatability or perceived knowledge of the messenger. A systematic review of nudges to improve clinical decision making found that in 16 of the 17 RCTs that used social norm and messenger effect resulted in improved clinical behaviour.[27] However, there are other contexts in which messenger effects have no effect.[49] To attempt to leverage messenger effects, 2 of the 7 decision information posters will include the image of two physicians (one male, one female) to convey credibility and trustworthiness of the information. These nudges aim to provide patients with information to help them weigh the costs and benefits, and to encourage them to engage in care decisions with their clinician.

Suggested alternatives involve increasing the salience of more preferable options that users can substitute the targeted behaviour with.[50] In our patient nudges we have suggested that instead of getting imaging and using opioids patients can use evidence based management techniques including gentle movement, using heat, and giving time.

The *Cues to action* used in the patient nudge intervention aim to reduce patient requests for imaging and opioid medicines and encourage patients to start a conversation about their care options with their ED clinician.[35] Our randomised proof-of-concept study found that, compared with standard care, these patient facing nudges reduced intention to request imaging by 1-point on a 10-point scale (95% CI, −1.6 to −0.4). [51]

All decision information posters will be translated into Arabic, Simple Chinese, and Vietnamese.[52] Up to two non-English language posters will be included in rotation in each of the sites based on the relevant LHD data on languages most spoken.

Appendix 1, as submitted by the authors. Appendix to: Altinger G, Sharma S, Maher CG, et al. Behavioural nudges to reduce low-value care for low back pain in the emergency department (NUDG-ED): a 2 × 2 factorial, pragmatic cluster randomized trial. *CMAJ* 2026. doi: 10.1503/cmaj.251595.

Clinician nudges: computer alerts

At ED sites randomised to receive clinician nudges, we will implement three small changes to the current computerised order systems that are triggered only for patients who are flagged in the workflow as presenting with back pain. Clinician Nudge A (Figure 4) is a prompted choice alert that appears when a clinician attempts to order any lumbar imaging test for a person with back pain. This acts as a decision support, reminding clinicians imaging is not routinely recommended, lists indications, and provides them with information resources. [See attachment List of red flags and information on safer care options]

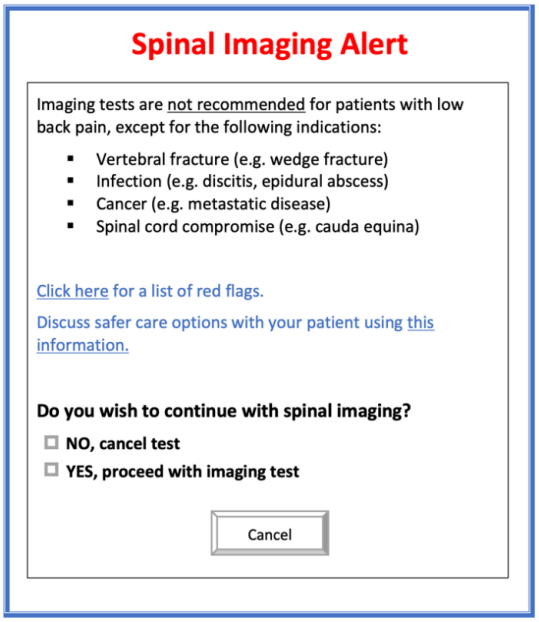
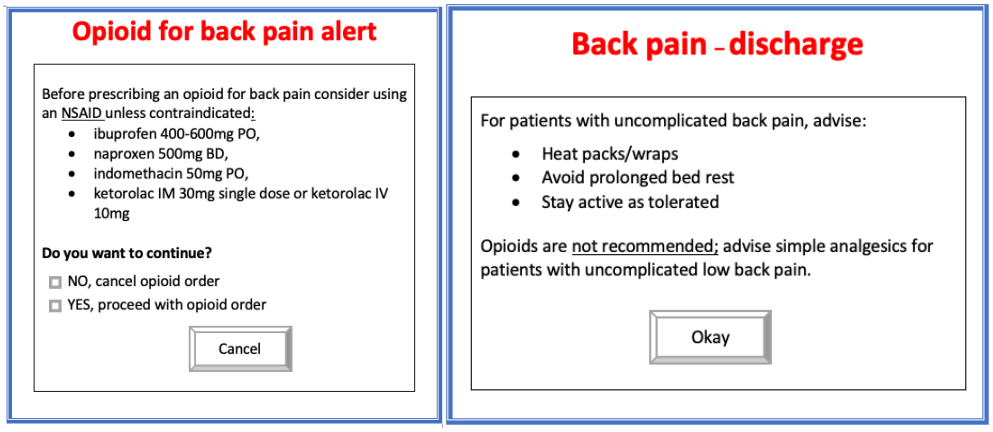


Figure 4: Clinician Nudge A- computerised alert when clinicians try to order imaging without serious pathology indicated. The pop-up reminds clinicians imaging is not recommended and includes a clickable link to the decision information brochure.

Clinician Nudge B is also a prompted choice alert that appears when a clinician attempts to administer an opioid medicine for a person with low back pain. Before proceeding with the administration, the alert reminds clinicians that opioids are not beneficial for back pain[11] and provides a list of suggested alternative medicines to choose from (Figure 5).

Clinician Nudge C appears when patients with back pain are being discharged. This alert also provides evidence-based advice on non-opioid care for patients at home.



Clinician Nudge B **Clinician Nudge C**

Figure 5: Clinician Nudge B- computerised alert when clinicians try to administer an opioid medication for back pain. The pop-up reminds clinicians opioids are not recommended and provides suggested alternatives for more appropriate care and Clinician Nudge C- computerised alert when patients with back pain are being discharged. This pop-up provides evidence-based advice on non-opioid care for patients at home

Theory and evidence behind the clinician nudges
The clinician nudges change the decision structure and provide decision assistance to clinicians at the time of decision making.[33] They take the form of active choice alerts that disrupt the habitual flow of test and/or opioid ordering and provide information to support decision making.

One of the reasons doctors provide unnecessary care is because of perceived patient pressure.[29] Clinicians worry that patients will complain if they don't receive complex care such as opioids or imaging. Another reason is *commission bias* effects.[53] Commission bias is the tendency to provide something, rather than nothing,[53] even when nothing is the clinically appropriate decision.[25] A cross-sectional survey study of 435 Emergency Physicians found that 97% reported that they had personally ordered some unnecessary imaging.[54] Common reasons for this were fear of litigation, having a preference to reduce uncertainty or the harms of commission being seen as less than the harms of omission. The imaging alert provides clinicians the option to provide their patient with the decision information brochure to attempt to alleviate *commission bias* effects (Figure 4). The opioid alert provides clinicians suggested alternatives to remind clinicians that safer care alternatives are available for them to provide (Figure 5).[50, 55] The imaging and opioid alerts aim to reduce effects of perceived patient pressure and commission bias effects by providing clinicians something (information and evidence based care alternatives) that they can provide patients.

If clinicians still decide to proceed with the imaging test after receiving the imaging alert, the physician must provide an *accountable justification*.[55-58] That is, they must provide a clinical indication for the test from a list of potential options (Figure 4). This alert *increases the option related effort* required to order imaging and acts as a *reminder* of the clinical indications for imaging according to current professional standards.[34] Clinicians may override the alert by selecting 'other' and simply provide a justification as free text if they wish.

Intervention delivery
In the first week of the 6-month intervention period PIs Traeger, Sharma and/or Altinger will visit the ED director at each intervention and control site and ensure the interventions have been implemented as planned. It is not possible to blind clinicians in the intervention groups to group allocation as they will be oriented to the functionality of the intervention. ED clinician participants in the intervention and control groups will be officially notified by their ED director of the start date and aims of the trial, and to give explicit support for the trial (Appendix 3).

An LCD advertising screen (55-inch) will be newly installed in the ED waiting room of each participating hospital. In hospitals randomised to receive the patient nudge intervention, the screen will begin displaying the decision information posters in the form of a slideshow on loop (~10 seconds per poster). Patients presenting with back pain will be able to access the decision information brochure via a QR code on the LCD screen and their smartphone. Paper versions of the decision information brochure will be supplied to waiting rooms if requested (some sites prefer to avoid leaflets in their waiting areas). At hospitals not allocated to the patient nudge intervention group, the screens will display standard hospital messaging. Investigators can launch and monitor the fidelity of the patient nudges remotely via web analytics and LCD advertising screen content management system.

Hospitals randomised to the clinician nudges will launch the computer alerts in ED. Interventions will run for 6-months at each intervention site.

5.5 Randomisation and group allocation
We will use cluster randomisation because the intervention will be at the hospital level. We will randomly allocate the 8 hospitals (clusters), into one of four groups: i) no intervention; ii) patient nudges; iii) clinician nudges; iv) patient nudges and clinician nudges. To create the randomisation list

a trial statistician will use computer-generated random numbers. At least one member of the research team and a blinded statistician will be unaware of site allocation. Outcome assessors and trial staff reviewing clinical notes will also be blind to site allocation.

5.6 Data collection

We will use Discern Analytics to build a standardised query to extract the routinely collected health service delivery data at participating sites from Cerner software. In the 3-month control period and during the intervention period, the same health service delivery measures will be extracted from all sites, every week, until the end of the trial at 6 months of follow-up. This collection system has worked well in our previous trial [21] and avoids additional workloads for ED staff. We will collect patient-reported outcomes from a random subsample of patients who presented during the 9mo trial period (n=456 or ~12% of sample). We will use automated text messaging to contact patients one week after the index ED visit. Participants will be referred to a brief self-reported online questionnaire. For the nested study of recruitment methods we will collect patient reported data from 1040 patients via text message.

5.7 Outcome measures

Primary outcome

The primary outcome will be use of low-value care, defined as the proportion of encounters for back pain due to a musculoskeletal condition where a person received a non-indicated imaging test, an opioid at discharge, or both, in ED over a 9-month period. We chose this composite outcome because it is a meaningful metric to ED clinicians. Clinician researchers will perform chart reviews every month using a standardised form for all participants who present with back pain and receive imaging to understand and code if it was *non-indicated* imaging (that is, imaging provided in the absence of clinical features of serious pathology) using reliable methods we have published.[46] Opioids at discharge for patients with low back pain will be coded as low-value.

For patient participants who received imaging, the following sections of the clinical chart will be examined, and used to code the primary outcome (Figure 6):

- Order comment
- Clinical or case notes
- Reason for imaging request
- ED discharge letter
- ED imaging report
- Hospital admission report

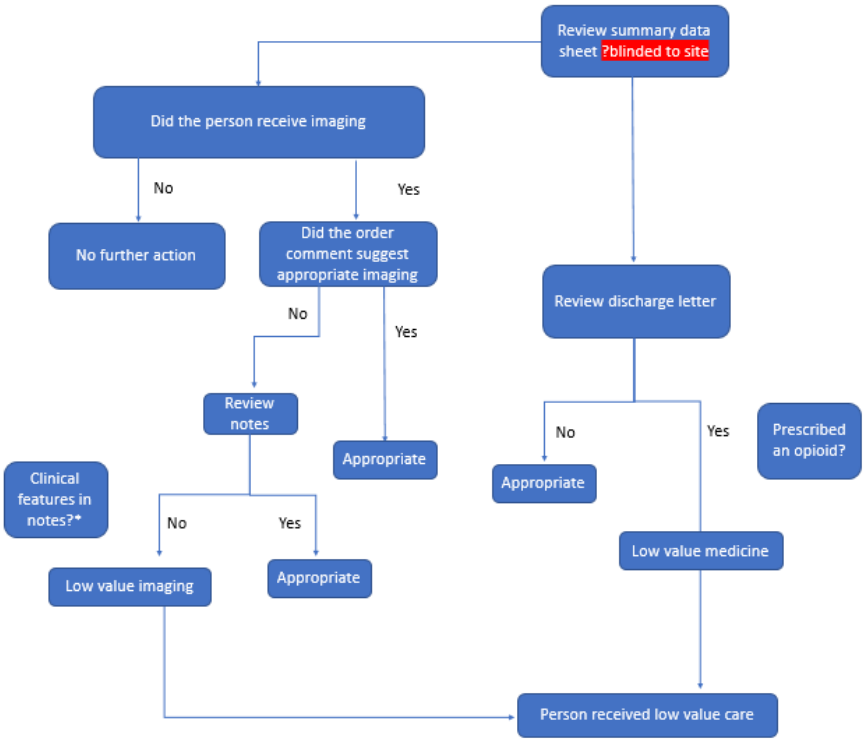


Figure 6: Decision tree for appropriateness of imaging and opioids

A clinician researcher will screen clinical charts of participants who received imaging and identify if there were documented clinical indications. To do this, the appropriateness of imaging will be coded via standardised chart review form via a REDCap link. Approved chart reviewers (clinician researchers) will receive a list of participants in the trial whose charts require review. This list, which will contain patient identifiers (MRN, DOB, Visit ID) and a unique link to the standardised chart review form, will be shared by NUDGED investigators with the approved chart reviewers (clinicians) using Kiteworks via NSW Health or The University of Sydney REDCap.

To assess appropriateness of opioids, clinician researchers will screen the discharge letters of all participants. As suggested by our ED clinician focus group, opioids provided at discharge will be coded as low value care for low back pain.

Once the required number of clinical charts have been screened, the patient ID will be deleted and replaced with a study participant ID prior to data analysis.

Appropriateness criteria will be based on international clinical guidelines[59] and our previous work[46].

* **Indications for urgent imaging**

Examine clinical notes in eMR for indications for *URGENT imaging, including* :
1. Emergency Department Triage notes
2. Emergency Department Case history

These are:

1) Documented suspicion of any of the following conditions
- Fracture
- Cauda equina
- Infection
- Malignancy

OR

2) Alerting features for **urgent** imaging in ACP guideline:

- Symptoms or signs of cauda equina syndrome (i.e. new bladder or bowel disturbance, saddle numbness, AND/OR lower motor neuron weakness)
- Symptoms or signs of infection (i.e. new onset of fever and history of intravenous drug use, RECENT spinal procedure, immunosuppression)
- **Major** risk factors for cancer [Hx of Ca that metastasises to bone (e.g., breast, lung, prostate); new onset of low back pain with Hx of Ca, multiple risk factors for cancer]
- **Major** risk factors for vertebral compression # (History of osteoporosis #, systemic long term steroid use, significant trauma, older age (>65 for men, >75 for women) – **multiple** features)

OR

3) Any of the following red flags relevant to Emergency Department setting:
- High-force trauma or minor trauma in older adults (>65 for men, >75 for women)
- >= 2 back pain presentations to Emergency Department in last month

Figure 7 Clinical features indicating imaging is required[46, 59]

Secondary outcomes

The following patient-reported outcome measures will be collected in a subsample of 456 patients up to one week after their index ED visit in the 3 month (~152 patients) before period and 6 month after period (~304 patients):

- **Patient experience** with emergency care (the 2-items related to 'Overall Assessment of ED Experience' and 2-items from 'Medical Provider' from 36-item Press Ganey ED Survey)[60]:

- **Pain intensity** using Numeric Pain Rating Scale of 0 to 10 with 0 indicating no pain and 10 indicating worst pain imaginable,[61] and disability measured using Henschke et al. 2008 adaptation of item 8 of the SF-36[62]:
    - During the past week, how much did low back pain interfere with your normal work (including both work outside the home and housework?)
      (Not at all, a little bit, moderately, quite a bit, extreme)
- How long have you had your current back pain problem? Tick one (Orebro Musculoskeletal Pain Questionnaire)
    - 0 to 1 week
    - 1 to 2 weeks
    - 3 to 4 weeks
    - 4 to 5 weeks
    - 6 to 8 weeks
    - 9 to 11 weeks
    - 3 to 6 months
    - 6 to 9 months
    - 9 to 12 months
    - Over 1 year

- **Health related quality of life** EQ-5D-5L asks participants to indicate how much trouble they are having in the following:[63]
    - *Mobility*
    - *Self-care*
    - *Usual activities*
    - *Pain/discomfort*
    - *Anxiety/depression*

- **Reassurance** provided using Generic reassurance subscale from consultation-based reassurance[64] asking participants to indicate on a 7-point Likert scale ranging from 'not at all' to 'a great deal':
    - *To what extent did the physician:*
        - *Tell you that you should not be worried*
        - *Tell you that everything would be fine*
        - *Reassure you that he/she had no serious concerns about your back*
    - *How reassured do you feel that there is no serious condition causing your back pain?[65] (On a 7-point Likert scale, ranging from 'not reassured at all' to 'completely reassured')*

- **Patient participation in decision-making** (CollaboRATE Tool) (10-point scale from 'No effort was made' to 'Every effort was made')[66]
    - *How much effort was made to help you understand your health issues?*
    - *How much effort was made to listen to the things that matter most to you about your health issues?*
    - *How much effort was made to include what matters to you in choosing what to do next?*

- **Referral to a specialist** provided with a combination of clinical notes review and patient reported diagnosis:
    - *Have you been referred to a specialist for the health condition you went to ED for?*
    - *If yes: Please indicate which specialist the referral was for (drop down menu)*
        - *Addiction Medicine Specialist (support with alcohol or substance use)*
        - *Cardiologist (heart conditions)*
        - *Endocrinologist (hormone related illness including diabetes)*
        - *Gastroenterologist or hepatologist (gastrointestinal and liver health)*
        - *General Practitioner (GP or family practice)*
        - *Geriatrician (older adult specialist)*
        - *Massage therapist (therapy for muscle issues)*
        - *Nephrologist (kidney health)*
        - *Neurologist (brain, spinal cord and nerves)*
        - *Obstetrician and Gynaecologist (health of women including during pregnancy)*
        - *Oncologist (cancer specialist)*
        - *Orthopaedic Surgeon (surgery for bone and joint issues)*
        - *Pain specialist*
        - *Palliative Medicine Specialist (chronic or terminal health conditions)*
        - *Physiotherapist or chiropractor (therapy for musculoskeletal issues)*
        - *Psychiatrist or psychologist (mental, emotional or behavioural support)*
        - *Radiologist (imaging specialist e.g. X-ray, CT Scan, MRI etc)*
        - *Rehabilitation Specialist (disability, mobility or injury support)*
        - *Rheumatologist (arthritis and joint health)*
        - *Surgeon (general)*
        - *Other (please specify)*

- **Intention to seek second opinion** measured using a question from national patient safety foundation, AMA[67]
    - *Thinking about experiences you have had with health care professionals, such as doctors, please tell me how likely or unlikely you are to get a second opinion? (very likely, somewhat likely, not very likely, not at all likely).*
    - *Did you see your GP/Physio after attending ED?*

- **Patient beliefs** about imaging and opioids for low back pain measured on 5-point Likert scale from 'strongly disagree' to 'strongly agree' for the following statements (two items from Jenkins et al. 2015):
    - X-rays or scans are necessary to get the best medical care for low back pain
    - Everyone with low back pain should have spine imaging (e.g. X-ray, CT or MRI)
    - [new statement] Opioid medicines are effective long term pain relievers for low back pain

Service outcomes

- Proportion of patients admitted to hospital (excludes patients sent to ED short stay units)
- Proportion of patients who receive advanced imaging tests (CT/MRI= yes, X-ray/no imaging= no)
- Time in ED (triage time to ED discharge or admission time, including the time in short stay units)
- Hospital costs (including intervention costs, that is, LCD screens, installation costs, staff time, IT support costs), cost-effectiveness
- Use of opioids in ED (eMeds)

Fidelity measures

- Engagement with computerised nudges including number of overrides. This will be measured using routine workflow data and assessing the number of computerised alerts shown vs number of computerised alerts overridden (i.e. the decision to prescribe opioids/imaging was unchanged)
- We will also measure clinicians' awareness and opinion of interventions via a survey in both intervention and control groups. The survey will be sent to clinicians by the ED Head of Department, and we will obtain consent from clinicians before they complete it. Depending on which group their hospital has been randomised into, clinicians will receive one of the following surveys:
  1) Clinician nudge group:
     a) *What is your role in the ED? (Junior Medical Officer, Registrar, Consultant, nurses, physiotherapists)*
     b) *Is it in your scope of responsibility to order imaging for back pain? [If no, then will not receive question f]*
     c) *Is it in your scope of responsibility to provide opioids for back pain? [If no, then will not receive question g] [If no to both b and c, then will not receive question e]*
     d) *Were you aware of the NUDG-ED trial being run in your department?*
     e) *How did you find the computerised alerts for back imaging and opioid prescribing? (Very unhelpful, unhelpful, helpful, very helpful)*
     f) *Did any patient refuse to have imaging when recommended?*
     g) *Did any patient refuse to take opioids when offered for pain relief?*
     h) *Do you have any additional comments or feedback on the trial?*

  2) Patient nudge group:
     a) *What is your role in the ED? (Junior Medical Officer, Registrar, Consultant, nurses, physiotherapists)*
     b) *Is it in your scope of responsibility to order imaging for back pain? [If no, then will not receive question f]*
     c) *Is it in your scope of responsibility to provide opioids for back pain? [If no, then will not receive question g]*
     d) *Were you aware of the NUDG-ED trial being run in your department?*
     e) *Did any patient refuse to have imaging when recommended?*
     f) *Did any patient refuse to take opioids when offered for pain relief?*
     g) *Do you have any additional comments or feedback on the trial?*

  3) Combined nudge group:
     a) *What is your role in the ED? (Junior Medical Officer, Registrar, Consultant, nurses, physiotherapists)*
     b) *Is it in your scope of responsibility to order imaging for back pain? [If no, then will not receive question f]*
     c) *Is it in your scope of responsibility to provide opioids for back pain? [If no, then will not receive question g] [If no to both b and c, then will not receive question e]*
     d) *Were you aware of the NUDG-ED trial being run in your department? [If no, then will not receive question e]*
     e) *How did you find the computerised alerts for back imaging and opioid prescribing? (Very unhelpful, unhelpful, helpful, very helpful)*
     f) *Did any patient refuse to have imaging when recommended?*
     g) *Did any patient refuse to take opioids when offered for pain relief?*
     h) *Do you have any additional comments or feedback on the trial?*

  4) Control group:

a) *What is your role in the ED?*
(Junior Medical Officer, Registrar, Consultant, nurses, physiotherapists)
b) *Is it in your scope of responsibility to order imaging for back pain? [If no, then will not receive question d]*
c) *Is it in your scope of responsibility to provide opioids for back pain? [If no, then will not receive question e]*
d) *Were you aware of the NUDG-ED trial being run in your department?*
e) *Did any patient refuse to have imaging when recommended?*
f) *Did any patient refuse to take opioids when offered for pain relief?*
g) *Do you have any additional comments or feedback on the trial?*

- We will also measure patient engagement with the QR code as a measure of fidelity

Unintended consequences

- Proportion of patients representing with low back pain to the ED within 48 hours
- Proportion of patients with unintended 30-day re-presentation
- Proportion of patients who are readmitted
- Proportion of patients who left the ED without treatment
- Proportion of patients diagnosed with non-musculoskeletal pain who were administered an opioid

Experiences with interventions

- Semi-structured interviews (15min via Zoom) with patients and clinician participants at each site to discuss implementation (usage, reactions to, and awareness of interventions) (n= ~40); we will attempt to capture clinician beliefs in their own capability, motivation, and opportunity to reduce low-value imaging and opioids (three adapted questions modelled on COM-B system)

5.8 Recruitment and Screening

Figure 8 summarises participant flow through the study, consent, data movement and other ethical considerations.

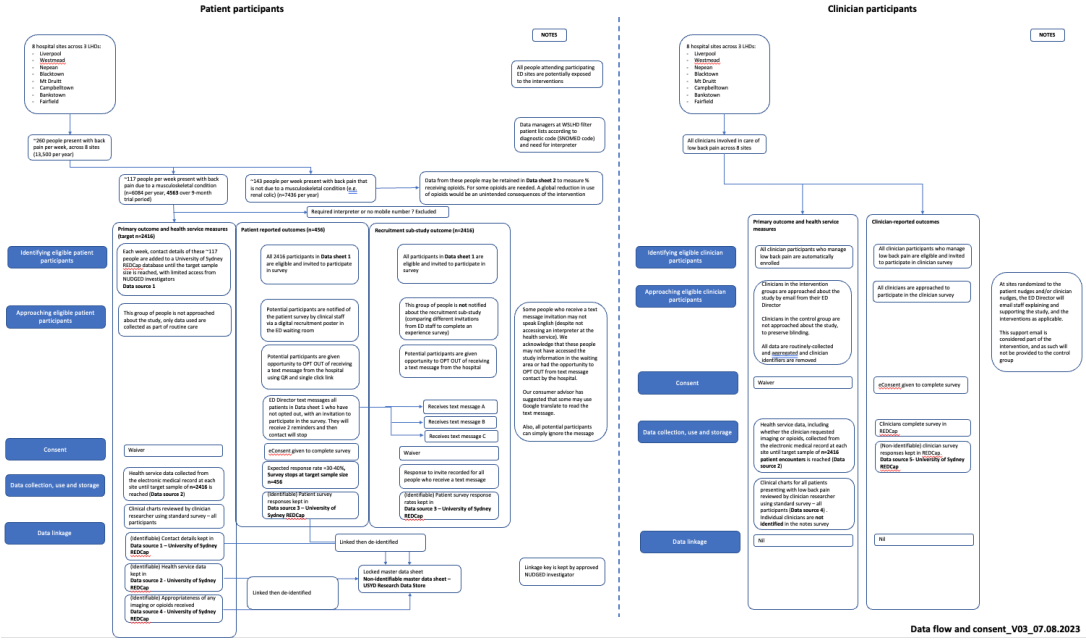


Figure 8: Summary of participant flow through the NUDGED Trial, consent, data movement and other ethical considerations (available as pdf in Attachment).

ED clinician participants
To remove the influence of being monitored in a trial from our main effect estimates, we will ask ED directors to announce the trial at month 4 at all sites, including in the "no intervention" hospitals. We will look at a (non-randomised) before-after comparison in the "no intervention" hospitals to estimate the magnitude of effect of being monitored in a study. After the intervention period, we will invite consenting ED clinicians to participate in semi-structured interviews. Clinician participants who participate in a post-trial interview will not be compensated because travel expenses are likely to be negligible (interviews will be conducted in Zoom). We will record and transcribe the interviews. We will use Zoom's audio transcribing feature to transcribe the recording.

Patient participants
Patient participants contributing to data to primary outcome
Our primary outcome is based on routinely collected data from all 2,416 encounters for back pain due to a musculoskeletal condition (see appendix 1 for definitions). We are seeking a waiver of consent to access these data. These patients will not be approached individually about the study as it is not feasible. They will be enrolled automatically when they attend a study site.

These 2,416 encounters will be identified by clinician investigators and an ED Data Manager who will select a consecutive sample of patients who were discharged with back pain and obtain their mobile phone number. This information will remain on secure REDCap servers. To confirm eligibility, clinician investigators will identify encounters for back pain due to a musculoskeletal condition using a list of SNOMED diagnostic codes (Appendix 1).

Patient participants contributing data to patient reported outcomes (secondary outcomes)
Some of our secondary outcomes are based on patient reported outcomes provided by a sub-set of patient participants (n=456). These participants will be approached by clinical staff involved in the care of the patient (i.e. the ED Director) in two ways. The first way is by a recruitment notice from the ED Director at each site which is shown on the 55" waiting room screen, and a recruitment notice attached to the end of the decision information brochure. (Appendix 2). Participants not wanting to receive a text will be given an opportunity to opt out via a QR code on the same recruitment notices. The second way is by text-message from the ED Director inviting potential participants to conduct a brief survey. After the initial contacts have been made by the ED Directors, participants who do not opt-out and do not respond to the text message invitations, a member of the research team will give participants a phone call on behalf of the clinical team. We have previously used these methods of approaching potential participants in ED, in previous studies approved by Sydney LHD HREC (2019/ETH08953 and X17-0043) and Southwestern Sydney LHD HREC (2019/ETH00281).

The ED Directors of participating hospitals will contact potential participants via text message, using a software program called Twilio. The message will include an invitation to participate and a link to "complete a survey about the care you received at our hospital and some materials we have had up in the waiting room." As per section 5.2 (Box 1), our nested study means patient participants could receive one of 3 different text message invitations.

All 2416 participants enrolled for the primary aspect of this study (see previous section) will be eligible to be approached for the patient surveys. People who required a translator service, people who opted-out in response to the waiting room notice and people who did not provide a mobile number at check-in, will be excluded.

We will invite all participants irrespective of cultural or language background, acknowledging that some of these people will not have accessed the English-language notice about the survey, and the opportunity to opt out, in the waiting room. However, rather than exclude these people from the study, we chose to invite them in the chance they could complete a survey with help from a family member. Also, our intervention materials at some sites will be translated into the top 2 non-English language groups for each hospital.

One week after the emergency presentation, ED Directors will text message patients (via Twilio) an invitation to participate and a link to an online quality improvement survey (via RedCap) which includes the Participant Information Statement and Consent Form, as well as a brief questionnaire. Participant Information Statement and Consent Form will be developed at a grade-8 reading level to make it suitable for those with low literacy.

At this point, patients might opt out by replying “NO” or “STOP” or refuse to participate via the link and will no longer be contacted. Completion of the online survey will indicate consent to participate in the study. Survey participants will complete the survey via a secure web-interface. Data will be captured in a RedCap database. Both the web-interface and RedCap database will be hosted on a secure server at The University of Sydney, with access restricted to the Investigators and data administrator.

This study automatically recruits and enrols participants who attend study sites with specific clinical characteristics (ie back pain due to a musculoskeletal condition) and assess the clinical care they receive. Although we will attempt to notify every potential participant via our waiting room posters from the ED director, it is possible some may not read this. Our hospitals are in diverse multicultural areas and so it will not be possible with our study design to reach all people and notify them of the study prior to enrolment. This means that (de-identified) data from these people would be assessed and analysed for the study, and they could possibly receive a text message about their experience, without knowing about the study in advance. However, we consider the risk of this causing distress to be low, and the benefits of the research (e.g. preventing harms to patients and diverting ED resources to urgent care) to outweigh this risk. All decision information posters will be translated into Arabic, Simple Chinese, and Vietnamese. Up to two non-English language posters will be included in rotation in each of the sites based on the relevant LHD data on languages most spoken. Also our decision information brochure has been developed at a grade 8 level.

5.9 Sample size

Previous study of patients presenting to ED with low back pain suggests 31.7% (95% CI 22.9 to 41.6)[68] received opioid prescription at discharge and 30.3% (95% CI 23.7 to 38.0) received non-indicated lumbar imaging[46]. To detect an effect of the patient nudges or clinician nudges on low-value care, with an effect size of 10% (e.g. event rate 30% in the control hospitals vs event rate 20% in intervention hospitals) and with 80% power, alpha set at 0.05, and assuming an intra-class correlation coefficient (ICC) of 0.10, and an intra-period correlation (IPC) of 0.09 (that is, between the before and after periods, within each site), and accounting for variable cluster sizes we would require 2416 encounters for back pain due to a musculoskeletal condition across 8 sites, over a 9-month trial period (ie, 302 encounters per site, over 3 month baseline and 6 month intervention period]) and stop recruitment once we have achieved our target sample size. Our sample is based on an achievable and conservative estimate that IPC is less than ICC and assumes no loss to follow-up. Losses to follow up are very unlikely because our primary outcome is based on routinely collected health service data.

For patient-reported outcomes, we calculated power based on the mean of 5-items related to ‘Overall Assessment of ED Experience’ of the Press Ganey Survey (range 1-5), at 1-week follow-up. We assumed a mean of 4.2 points, a SD of 1.9,[69] a non-inferiority margin of 0.5-point (i.e. 0.5-units is the maximum acceptable drop in patient experience), an IPC and ICC of 0.01, the required sample size for 80% power, is 57 patients per site, over the 6-month intervention period (456 patients in total). The expected response rate of the survey is around 50%.[21]

5.10 Site recruitment

We adopted a pragmatic approach to site selection. We recruited sites based on the capacity of the sites to make eMR changes. We selected Western Sydney Local Health District and Nepean Blue Mountains Local Health District because they share the same eMR, and Southwest Sydney Local Health District because of investigator links at those sites.

5.11 Blinding

It is not possible to blind patient participants to the nudge interventions, though measures will be taken to reduce performance bias e.g. masking patients and clinicians to the study hypothesis. Study personnel involved in reviewing and coding health service data for the primary outcome will also be blinded. Statistical analysis and interpretation will also be performed blind to group allocation. Unblinding will occur once data analysis and interpretation are complete.

5.12 Data collection methods

Health-service data

Using electronic clinical charts, a data manager at each of the 8 participating sites will extract the following re-identifiable data on people presenting with back pain, to a password protected Excel spreadsheet:

1. Patient ID (unique code to be converted to Study ID)
2. First name
3. Mobile number
4. Encounter ID
5. Age
6. Sex Country of birth
7. Interpreter required
8. Postcode
9. Admit date and time
10. Left without treatment (Y/N)
11. Visit ID
12. Multi present flag
13. MRN
14. Triage category
15. Presenting problem
16. ED mode of arrival
17. ED Diagnosis
18. Encounter type
19. Facility
20. Orderables
21. Order comment
22. Order date and time
23. Order ID
24. Opioid administered Time in short stay unit (hours)
25. Length of stay in ED (minutes)
26. Discharge date and time
27. Admitted to hospital
28. Discharge summary

Clinical notes and coding of appropriateness

Clinical notes will be accessed by approved NUDG-ED investigators using remote access to the eMR.

For participants who received a potentially non-indicated imaging test (see Figure 6), the approved NUDG-ED investigators will read the relevant sections of the clinical notes and discharge summary and complete a standardised chart review form to code appropriateness as described in the *Primary Outcomes* section using a link via REDCap.

Patient reported data

We will collect patient reported data via a secure web application, REDCap. We will send participants a text message invitation via Twilio to participate and a REDCap link to complete an online survey.

Data sources

1. Data sources 1 and 2 (patient contact list and health service datasheet)

We will receive patient contact list and health service datasheet from Clinical Analytics teams via ‘Kiteworks' and will be uploaded directly into REDCap which only three approved investigators and a Database Administrator at the NHMRC Clinical Trials Centre at the University of Sydney (who is helping us build the trial database in the University of Sydney REDCap) can access. Kiteworks is a secure portal used by LHDs to transfer secure sensitive data via email. This data received from Kiteworks will then be transferred to REDCap database hosted by The University of Sydney. REDCap is suitable for "highly protected" data – data is stored securely, is encrypted in transit and at rest, and resides within the University. REDCap has been approved by ICT as suitable for data classified as "highly protected" under the data classifications. REDCap projects are backed up automatically on the University servers on a regularly scheduled basis. The backup data files are kept

in a secure environment and are available for recovery. REDCap database will only be accessible to researchers that have the appropriate approvals to access the data (Figure 9). Some identifiable information from LHD servers will be moved to a primary database hosted by the University of Sydney REDCap. Our colleagues leading a similar trial in SLHD have successfully and securely transferred identifiable hospital data to USYD REDCap (ID X23-0143, Sydney Local Health District Ethics Review committee). Their risk mitigation measures include using the REDCap function of the Master Code Sheet Project Template for the storage of identifiable patient data which will generate a re-identifiable record within a separate research data project in REDCap using a participant identifier. Confidentiality will be maintained as all data will only be re-identifiable through the master coded sheet. All data will be uploaded directly into the REDCap database for storage purposes. The coordinating principal investigator will ensure confidentiality is maintained.

Only the REDCap administrator and three approved members of the NUDGED trial team will have access to the identifiable data within the REDCap database. Our experienced Clinical Data Systems Project Manager from the NHMRC Clinical Trials Centre will oversee and manage the secure transfer of data to the University of Sydney REDCap. The Clinical Trials Centre have expertise with oversight and management of sensitive clinical data on the University of Sydney REDCap.

2. Data source 3 (Patient Survey)
Patients will complete a voluntary online survey in the University of Sydney REDCap via a unique link they receive via SMS. This data will be collected directly via REDCap. Only approved investigators can access the survey. We will remove participant identifiers from the REDCap before exporting to the appropriate software for analysis (Figure 9).

3. Data source 4 (Patient's Clinical Charts)
Approved chart reviewers (clinician researchers) will access patients' clinical notes remotely via secure login using Stafflink number and password. These clinical notes will not be saved or downloaded, will only be read and for coding purposes. The appropriateness of imaging will be coded via standardised chart review form in REDCap. Approved chart reviewers will receive a list of participants in the trial whose charts require review. This list, which will contain patient identifiers (MRN, DOB, Visit ID), will be shared by NUDGED investigators with the approved chart reviewers (clinicians) using Kiteworks via NSW Health or REDCap (Figure 9).

4. Data source 5 (Clinician survey)
Clinicians will complete a voluntary online survey in the University of Sydney REDCap via a unique link they receive via email from their ED Director.

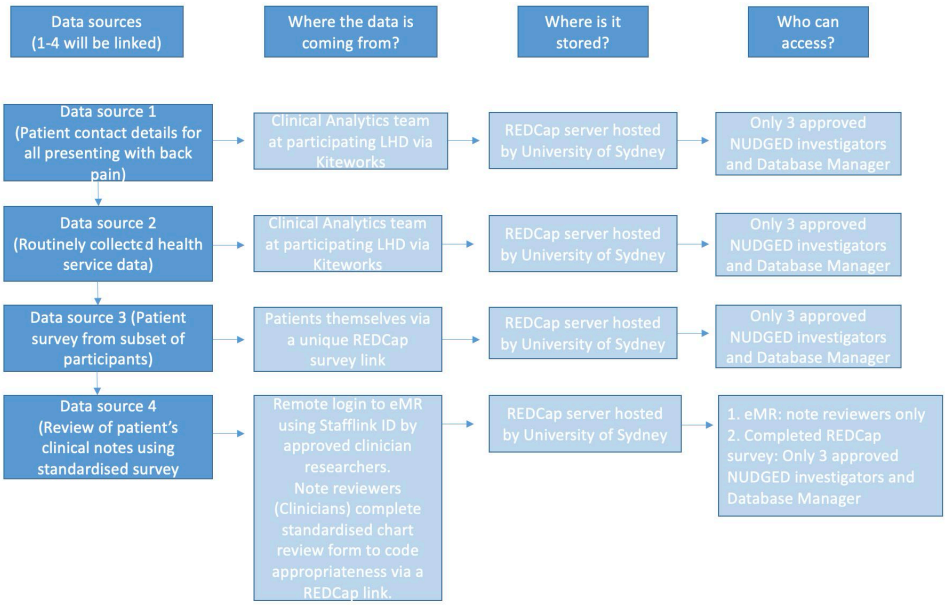


Figure 9: Data flow showing the types, source, storage and access of data

5.13 Data management
All data will be securely stored, with restricted access. Patient reported outcomes will be directly collected via the University of Sydney REDCap. Only the study investigators will have access to the data using a personal login and password. We will archive de-identified data at the University of Sydney for 15 years, and securely destroyed after that.

5.14 Statistical methods
Data analysis will be blinded, by intention-to-treat and guided by a published statistical analysis plan. Analysis will be conducted by an independent biostatistician and checked for accuracy.

- *Primary analysis:* to evaluate the effect of the intervention on the proportion of encounters for back pain due to a musculoskeletal condition where low-value care was provided, we will use a multi-level regression model, with a random effect for cluster and patient (assuming some patients may have several encounters during the study period), a fixed effect indicating the group assignment of each cluster and a fixed effect of time.
- *Secondary analysis:* dichotomous outcomes will be compared between groups using generalised estimating equations (GEE) considering clustering effects. Continuous secondary outcomes will be analysed using the same GEE model with appropriate link function.
- *Cost-effectiveness analysis:* cost- effectiveness analysis of the NUDG-ED interventions compared with current emergency care will be done from the health system perspective. For this, we will measure all costs related to the delivery of the intervention (that is, LCD screens, installation costs, staff time, printed resources, IT support). We will also calculate the costs of imaging and opioid use in control and intervention groups. We will present the incremental cost-effectiveness ratio (ICER) as the incremental cost per patient avoiding low-value care. We will also estimate the incremental cost per quality adjusted life year (QALY) gained, using utility weights from the EQ-5D-5L.
- *Process analysis:* a mediation analysis will estimate the extent to which intervention effects (or lack of effects) can be explained by changes in 1) patient beliefs, 2) patient reassurance, 3) clinician engagement with computer alerts, 4) perceived helpfulness of the computer alerts.

5.15 Auditing
We have not planned a formal audit. However, we will arrange independent auditing of the trial process and documents if needed.

6. END-USER INVOLVEMENT
Patient nudges have been co-designed with patients, public and clinicians. Two Consumer Advisors have been appointed to support throughout key stages of the research including reviewing the protocol and patient-reported outcome measures, analysing patient survey feedback and interpreting results.

7. ETHICAL CONSIDERATIONS
7.1 Confidentiality and Privacy
Please see Figure 8 which describes some the key ethical considerations, relating to consent and movement of data in the NUDGED trial

Quantitative component
Data from clinical charts cannot be de-identified, but will not be stored, only read by approved trial staff for coding purposes. Charts will be initially coded according to the MRN, Visit ID and date of birth, so that clinician researchers can match the clinical charts with a patient identifier in the spreadsheet and complete a standardised chart review form to code appropriateness as described in the *Primary Outcomes* section using a link via REDCap.

We will not collect any identifying information from the clincian participants for the clinician survey and interview to avoid potential for their responses to be identified.

Qualitative component
The identity of interview participants will be made anonymous by giving each participant a subject number. These subject numbers will be used for the data collection process. The master list of participants will be stored separately to the REDCap database on a secure server at the University of

Sydney. When analysing the interview data, the identity of clinicians participating in the project will not be revealed to PIs who are also staff members at the participating hospitals.

Confidentiality and privacy will be maintained by secure data storage (see section 7.2) and using non-identifiable data in the analysis and reporting. The codes will be linked to the participants' contact details, but these will be stored in a separate spreadsheet in REDCap which is password protected. This data will be stored in this way so that we can identify and match quotes from participants for the write up of the results. Only members of the research team will have access to the codes.

7.2 Data storage and record retention
We will adhere to the Australian Code for the Responsible Conduct of Research for the storage and archiving of data. All the data will be in digital formats. The digital records will be stored on a secure server at the University of Sydney with access restricted to the Investigators. The RedCap database and other data files will also be stored on a secure server at the University of Sydney, with access restricted to the Investigators. Data files will be coded. While the data are stored on the University of Sydney server, they are owned by the respective Local Health Districts participating in NUDGED. After 15 years of storage, the data will be securely destroyed.

8. FUNDING

This study is funded from the Australian National Health and Medical Research Council Clinical Trials and Cohort Studies grant ($1,119,327).

9. ENDORSEMENT

The trial has been endorsed by Australia New Zealand Musculoskeletal Clinical Trials Network.

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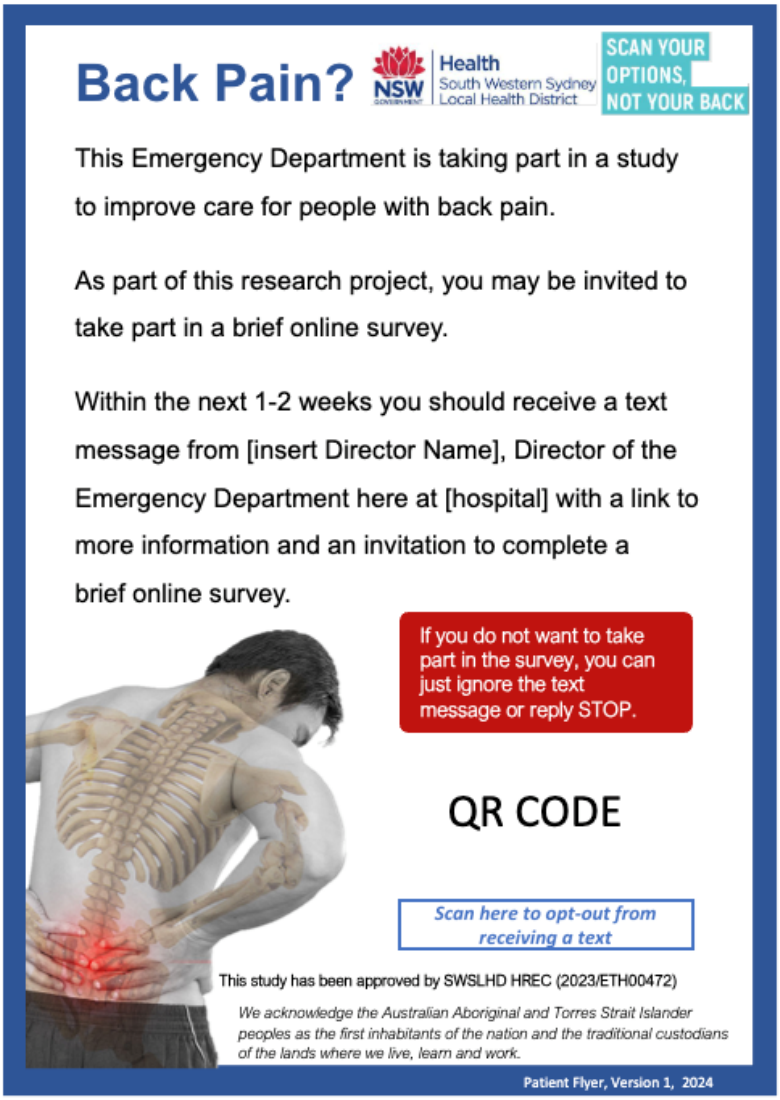
Appendix 1: Back pain categories based on Systematised Nomenclature of Medicine Clinical Terms Australia (SNOMED-CT AU) diagnosis

Low back pain due to a non-specific cause
Acute back pain - lumbar
Acute low back pain
Back ache
Back pain
Back pain complicating pregnancy
Back sprain
Backache
Buttock pain
Chronic back pain
Chronic low back pain
Chronic lower back pain
CLBP - Chronic low back pain
Displacement of lumbar intervertebral disc without myelopathy
Exacerbation of backache
IVDP - Intervertebral disc prolapse
Injury of coccyx
Intervertebral disc prolapse
Intervertebral disc protrusion
LBP - Low back pain
Low back pain
Low back strain
Lower back injury
Lumbago
Lumbago with sciatica
Lumbar back sprain
Lumbar pain
Lumbar spondylosis
Lumbar sprain
Lumbar strain
Lumbosacral sprain
Mechanical low back pain
Pain in back
Pain in buttock
Pain in coccyx
Pain in the coccyx
Sacral back pain
Sacrum sprain
Slipped disc
Spasm of back muscles
Sprain of sacrum
Strain of back muscle
Low back pain with neurological signs and symptoms
Acute back pain with sciatica
Acute sciatica
Chronic sciatica

Compression of lumbar nerve root
Low back pain co-occurrent with left side sciatica
Low back pain with left sciatica
Lumbago-sciatica due to displacement of lumbar intervertebral disc
Lumbar disc prolapse with myelopathy
Lumbar disc prolapse with radiculopathy
Lumbar disc prolapse with root compression
Lumbar radiculopathy
Lumbar spinal stenosis
Sciatica
Sciatica neuralgia
Spinal stenosis of lumbar region
Serious spinal pathology
Blunt injury to back
Cauda equina syndrome
Cauda equina syndrome with neurogenic bladder
Closed fracture lumbar vertebra
Compression fracture of lumbar spine
Crush fracture of lumbar vertebra
Discitis
Fracture of coccyx
Fracture of lumbar spine
Fracture of lumbar spine and pelvis
Fracture of lumbar vertebra
Fracture of sacrum
Fracture of transverse process of lumbar vertebra
Injury of cauda equina
Intervertebral discitis
Sacral nerve root injury - S1

Appendix 2: Patient opt-out poster from receiving patient reported outcome invitation



Appendix 3: Email from ED Director notifying all ED clinicians of trial at the start of the intervention period

Dear all,

A new clinical trial will be starting shortly at [insert hospital name] Hospital, Emergency Department (ED). The trial is titled: *NUDG-ED: Trial of behavioural 'nudging' interventions to reduce low-value care for low back pain in the Emergency Department*.

The trial is a collaboration between researchers at The University of Sydney (Dr Adrian Traeger, Senior Research Fellow; Ms Gemma Altinger, PhD Student; Dr Sweekriti Sharma, Research Fellow; Prof Chris Maher, Professor) and ED clinicians in 8 EDs across 3 LHDs.

The trial will investigate effectiveness of behavioural interventions to improve care for low back pain in the ED. We have be allocated to the [insert group] which means that [insert the description of the interventions/control…"we will receive some pop-up alerts when we try to request imaging or opioids for people with back pain" and/or "in the waiting room, some posters will be showing that discourage overuse of imaging for simple back pain, and explain to patients when imaging is needed". The aim of these interventions is to reduce the use of opioids at discharge and non-indicated imaging tests.

I fully support this trial and encourage you to engage in conversations with your patients about the need for imaging and/opioids, and use the patient information available to you [insert link to patient leaflet] (if allocated to intervention group).

Part of this study involves talking to clinicians, patients about their experience of the interventions. Once the trial is complete I will contact you again about taking part in a short survey with the researchers from the University of Sydney,.

Please contact Dr Adrian Traeger (adrian.traeger@sydney.edu.au, ph: xxxx), Dr Sweekriti Sharma (sweekriti.sharma@sydney.edu.au, ph: xxxx), or myself with any queries or concerns.

Regards,

[Insert ED Director Name]
Director of Emergency Medicine
XX Hospital

The conduct of this study at *[insert hospital name]* Hospital has been authorised by the South Western Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on (02) 8738 8304, email: SWSLHD-Ethics@health.nsw.gov.au and quote project number 2023/ETH00472, HREC Code XX.

Supplement 2: Statistical Analysis Plan

Behavioural 'nudging' interventions to reduce low-value care for low back pain in the Emergency Department
(NUDG-ED)

Statistical Analysis Plan (SAP)

Version: 0.7

Date: 25 March 2025

Authors:
Qiang Li, Sweekriti Sharma, Gemma Altinger, Chris Maher, Adrian Traeger, on behalf of the NUDG-ED Investigators

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Table of Contents

1 Administrative information

1.1 Study identifiers

- Protocol Number:
- Australian New Zealand Clinical Trials Registry Identifier: ACTRN 12623 00100 0695.

1.1 Revision history

Version	Date	Details
0.1 (draft)	5 January 2025	First draft by Q Li
0.2 (draft)	5 February 2025	Second draft reviewed by A Traeger
0.3 (draft)	10 March 2025	Third draft reviewed by Chris Maher and A Traeger
0.4 (draft)	10 March 2025	Fourth draft reviewed by C Maher, S Sharma, A Traeger, G Altinger
0.5 (draft)	21 March 2025	Fifth draft by blinded data review
0.6 (draft)	24 March 2025	Sixth draft by A Traeger, S Sharma, Q Li, C Maher
0.7 (final)	25 March 2025	Final draft by A Traeger, S Sharma, Q Li and agreed to by all

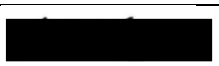
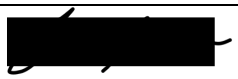
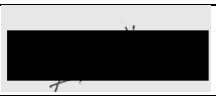
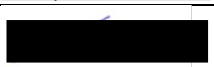
1.2 Contributors to the statistical analysis plan

1.2.1 Roles and responsibilities

Name and ORCID	Affiliation	Role on study	SAP contribution
Qiang Li	The George Institute for Global Health, UNSW Sydney	Study statistician	Prepared initial draft and revisions
Adrian Traeger	Institute for Musculoskeletal Health, School of Public Health, Faculty of Medicine and Health, The University of Sydney	Program investigator	Reviewed and approved final version
Sweekriti Sharma	Institute for Musculoskeletal Health, School of Public Health, Faculty of Medicine and Health, The University of Sydney	Research fellow, project coordinator	Reviewed and approved final version
Gemma Altinger	Institute for Musculoskeletal Health, School of Public Health, Faculty of Medicine and Health, The University of Sydney	PhD student	Reviewed and approved final version
Chris Maher	Professor, School of Public Health, Faculty of Medicine and Health, Central Sydney (Patyegarang) Precinct	Director, Institute for Musculoskeletal Health	Reviewed and approved final version

1.2.2 Approvals

The undersigned have reviewed this plan and approve it as final. They find it to be consistent with the requirements of the protocol as it applies to their respective areas. They also find it to be compliant with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) topic E9 Statistical Principles for Clinical Trials. In particular, we confirm that this analysis plan was developed in a completely blinded manner, that is without knowledge of the effect of the intervention(s) being assessed.

Name	Signature	Date
Qiang Li		25/03/2025
Gemma Altinger		25.3.25
Sweekriti Sharma		25/3/25
Chris Maher		25/3/25
Adrian Traeger		25/3/25

2 Introduction

2.1 Study synopsis

NUDG-ED is a 2×2 factorial, before-after, cluster randomised trial that aims to determine, for people with back pain due to a musculoskeletal condition presenting to Emergency Department (ED), the effectiveness of patient nudges, clinician nudges or both interventions compared with no nudge intervention on reducing encounters involving low-value care (non-indicated lumbar imaging test, opioid at discharge or both). The full protocol was published by BMJ OPEN in April 2024 [1].

2.2 Study population

A total of around 3700 encounters for back pain due to a musculoskeletal condition across 8 sites over a 9-month study period (3mo before period and 6mo after period) will be required.

2.2.1 Clinician participants

Clinician participants will be ED clinicians at study sites who are involved in the care of patients presenting to the ED with a primary complaint of low back pain. This includes physicians (Junior Medical Officer, Registrar, Consultant, Career Medical Officers), Nurses, and Physiotherapists. After the intervention period, ED Directors will invite all ED clinicians to complete a survey and a subset to participate in semi-structured interviews. We will be utilising a purposive sampling approach for clinician interviews to ensure a diverse range of clinician experience, age, gender, and interest in the management of back pain. We do not have capacity to collect data on individual clinician characteristics because these details are not recorded in the current eMR system.

2.2.2 Patient participants

For the health service measures, including our primary outcome, patient participants will be adults aged 18 years or over who present to the ED during the study period with back pain and who are subsequently diagnosed with back pain due to a musculoskeletal condition. To confirm eligibility, clinician investigators will use a list of Systematized Nomenclature of Medicine (SNOMED) diagnostic codes that correspond with back pain due to a musculoskeletal condition (Supplementary table 1 in the protocol paper). Patients will be included in the trial if they have a diagnostic code in one of three main categories of back pain due to a musculoskeletal condition: 1. Low back pain with non-specific cause; 2. Low back pain with neurological signs and symptoms; or 3. Low back pain due to serious spinal pathology (e.g. vertebral fracture, vertebral infection). For patient-reported outcomes, participants will be a subset of eligible patients presenting during the study period, who had a mobile phone number on record, who did not require a translator, did not opt out of the patient survey in the ED waiting room, and who responded to the study invitation.

2.3 Study interventions

2.3.1 Randomisation

We will use cluster randomisation because the intervention will be at the hospital level. We will randomly allocate the 8 hospitals (clusters), into one of four groups: i) patient nudges; iii) clinician nudges; iv) patient nudges and clinician nudges, iv) no nudge control. To create the randomisation list a trial statistician will use computer-generated random numbers.

2.3.2 Study intervention

Patient nudges were 6 digital decision information posters displayed on 55-inch LCD screens (Patient Nudge A – Figure 2 in the protocol paper) and a decision information brochure (Patient Nudge B – Figure 3 in the protocol paper) based on behavioural economics theory. Patients could access Patient Nudge B using their smartphone via a QR code on the digital posters. “Scan here for more information” is on each poster to direct patients to the patient information brochure.

Clinician nudges were alerts triggered in the ED clinician's ordering system when they attempted to order imaging or opioids for people with a presenting problem of back pain and at discharge of patients with back pain (See Page 7 in the protocol paper).

2.4 Outcomes

2.4.1 Primary outcome

The primary outcome will be use of low-value care, defined as the proportion of encounters for back pain due to a musculoskeletal condition where a person received a non-indicated lumbar imaging test, an opioid at discharge, or both, in the ED over a 9-month period. We chose this composite outcome because it is a meaningful metric to ED clinicians. Clinician researchers will perform chart reviews every month for all participants who present with low back pain and receive imaging to understand and code if it was non-indicated imaging (that is, imaging provided in the absence of clinical features of serious pathology) using reliable methods we have published [2]. Opioids provided or prescribed at discharge for patients diagnosed with 'non-serious' low back pain (i.e., Low back pain with non-specific cause; or 2. Low back pain with neurological signs and symptoms – See Supplementary table 1 in the protocol paper) will be coded as low-value.

Coding for primary outcome from CRF database:

Low value care = 0 (No) if any of three conditions below,

1. orderable (lumbar imaging) ='no value' from Datasheet upload form AND admitted=Yes OR clinopiod (Was the patient prescribed an opioid at discharge?)=No from Chart Review form;
2. orderable (lumbar imaging) ='any value' from Datasheet upload form AND clincond (Did the notes document suspicion of any of the following conditions?)=(1 to 4) from Chart Review form AND admitted= Yes OR clinopiod (Was the patient prescribed an opioid at discharge?)=No from Chart Review form;
3. orderable (lumbar imaging) ='any value' from Datasheet upload form AND clinqu7 (Were there any alerting features for urgent imaging in ACP guideline?)=(1 to 6) from Chart Review form AND admitted= Yes OR clinopiod (Was the patient prescribed an opioid at discharge?)=No from Chart Review form;

Low value care = 1 (Yes) if Imaging without indications or an opioid at discharge or both,

1. orderable (lumbar imaging) ='any value' from Datasheet upload form AND clincond (Did the notes document suspicion of any of the following conditions?)=5 AND clinqu7 (Were there any alerting features for urgent imaging in ACP guideline?)=7 from Chart Review form;
2. clinopiod (Was the patient prescribed an opioid at discharge?)=Yes from Chart Review form AND admitted= No;

If missing for all four choices below, this should be treated as "None" for clincond.

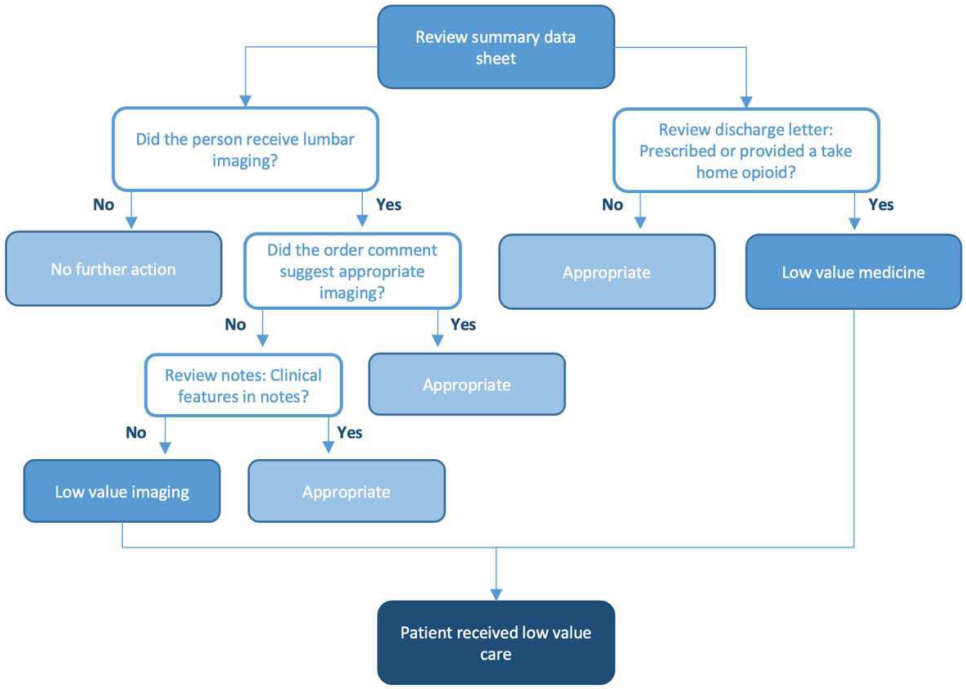
clincond___1	Did the notes document suspicion of any of the following conditions? (choice=Fracture)
clincond___2	Did the notes document suspicion of any of the following conditions? (choice=Cauda equine)
clincond___3	Did the notes document suspicion of any of the following conditions? (choice=Infection)
clincond___4	Did the notes document suspicion of any of the following conditions? (choice=Malignancy)

If missing or "none" for all six choices below, this should be treated as "None" for clinqu7

clinqu7___1	Were there any alerting features for urgent imaging according to current clinical guidelines? (choice=Symptoms or signs of cauda equina syndrome (i.e. new bladder or bowel disturbance, saddle numbness, AND/OR lower motor neuron weakness))

clinqu7___2	Were there any alerting features for urgent imaging according to current clinical guidelines? (choice=Symptoms or signs of infection (i.e. new onset of fever and history of intravenous drug use, RECENT spinal procedure, immunosuppression))
clinqu7___3	Were there any alerting features for urgent imaging according to current clinical guidelines? (choice=Major risk factors for cancer [history of cancer that metastasises to bone (e.g., breast, lung, prostate); new onset of low back pain with history of canc
clinqu7___4	Were there any alerting features for urgent imaging according to current clinical guidelines? (choice=Major risk factors for vertebral compression (History of osteoporosis, systemic long term steroid use, significant trauma, older age (>65 for men, >75 for
clinqu7___5	Were there any alerting features for urgent imaging according to current clinical guidelines? (choice=High force trauma)
clinqu7___6	Were there any alerting features for urgent imaging according to current clinical guidelines? (choice=Minor trauma in older adults (>65 for men, >75 for women))

Reference: Supplementary figure 2 in the protocol paper



2.4.2 Secondary outcomes

Patient reported outcomes

A number of patient-reported outcome measures include:

- Patient experience: 2-items related to 'Overall Assessment of ED Experience' and 2-items from 'Medical Provider' from 36-item Press Ganey ED Survey.
- Pain intensity: Numeric Pain Rating Scale, the pain duration question from Orebro Musculoskeletal Pain Questionnaire and disability measured using Henschke et al. 2008 adaptation of item 8 of the SF-36 health survey.
- Health related quality of life: EQ-5D-5L indicators.
- Reassurance: Generic reassurance subscale from Consultation-based Reassurance Questionnaire.
- Patient participation in decision making: CollaboRATE Tool.

- Referrals to specialist.
- Intention to seek second opinion: 1-item from the national patient safety foundation, AMA.
- Patient beliefs about imaging and opioids: item 13 and 14 from Jenkins et al. 2015 survey and a new statement on patient beliefs on the effectiveness of opioids.

Health service outcomes

- Proportion of encounters with an admission to hospital (ie 'admitted' variable = text, should be YES if any value)
- Proportion of encounters with any lumbar imaging test (ie 'orderable' variable = text, should be YES if any value)
- Proportion of encounters with an advanced lumbar imaging tests (ie, for 'orderable' variable, CT/MRI=YES, X-ray/no imaging=NO).
- Time in the ED (ie 'stayed' in minutes)
- Proportion of encounters with an opioid medicine prescribed or administered in the ED (ie 'opioid' variable = YES if any value; = NO if empty)
- Proportion of encounters with an NSAID medicine prescribed or administered in the ED (ie 'othermed' variable list an NSAID variable = YES, if no NSAID listed = NO)
- Proportion of encounters that were a 30 day reattendance [if 'reattend30d' or 'reattend48hr' = Yes, then should be Yes to 30 day reattendance]
- Proportion of encounters for *non-musculoskeletal pain* with an opioid medicine prescribed or administered in the ED [ie, 'snomedyn' = **no** AND 'opioid' variable = yes, then value = YES]
- Proportion of encounters where person left without treatment [ie, 'snomedyn' = **yes** AND 'notreatyn' variable = yes, then value = YES]

2.4.3 Tertiary outcomes

- Other process measures and service outcomes are not covered in this statistical analysis and will be analysed separately.

3 Analysis principles

3.1 Sample size

A previous study of patients presenting to ED with low back pain suggests 31.7% (95% CI 22.9 to 41.6) received opioid prescription at discharge and 30.3% (95% CI 23.7 to 38.0) received non-indicated lumbar imaging. To detect an effect of the patient nudges or clinician nudges on the number and proportion of encounters involving low-value care, with an absolute difference of 10% (e.g. event rate 30% in the control hospitals vs event rate 20% in intervention hospitals) and with 80% power, alpha set at 0.05, and assuming an intra-class correlation coefficient (ICC) of 0.10, and an intra-period correlation (IPC) of 0.09 (that is, between the before and after periods, within each site), and accounting for variable cluster sizes we would require 2416 encounters for back pain due to a musculoskeletal condition across 8 sites, over a 9-month trial period (i.e., ~302 encounters per site, over 3 month baseline and 6 month intervention period). Our sample is based on an achievable and conservative estimate that IPC is less than ICC and assumes no loss to follow-up. Losses to follow up are very unlikely because our primary outcome is based on routinely collected health service data.

For patient-reported outcomes, we calculated power based on the mean of 5-items related to 'Overall Assessment of ED Experience' of the Press Ganey Survey (range 1-5), at 1-week follow-up. We chose this measure because patient experience is a key priority for hospitals in Australia and have powered the study to detect a meaningful drop in patient experience due to either intervention. We assumed a mean of 4.2 points, a SD of 1.9, a non-inferiority margin of 0.5-point (i.e. 0.5-units is the maximum acceptable drop in patient experience), an IPC and ICC of 0.01, the minimum required sample size for 80% power, is 57 patients per site, over the 6-month intervention period (456 patients in total). The expected response rate of the survey is around 30-50%.

3.2 Software

Analyses will be conducted primarily using SAS 9.4 on SAS Enterprise Guide (version 8.3 or above).

3.3 Interim analyses

No interim analysis was planned to look at the efficacy of treatment until the final analysis.

3.4 Multiplicity adjustment

No multiplicity adjustment is planned for secondary outcomes.

3.5 Data sets analysed

3.5.1 Analysis populations

- The ***intention-to-treat (ITT) population*** is defined as all eligible patients of the randomised ED, and excluding those who withdrew their consent for any data to be used.

3.5.2 Analysis strategy

For all outcomes, the analyses will be performed on the ITT population using complete case analysis. No imputation is planned for missing data.

4 Planned analyses

4.1 Subject disposition

The flow of patients through the trial will be displayed in a Consolidated Standards of Reporting Trials (CONSORT) [3] diagram (see Figure 1). The report will include: the number of screened patients who met study inclusion criteria and the number of patients included, and reasons for exclusion of non-included patients.

4.1 Patient characteristics and baseline comparisons

Baseline characteristics will be summarised by intervention groups (see Table 1). Discrete variables will be summarised by frequencies and percentages. Percentages will be calculated according to the number of patients for whom data are available. Continuous variables will be summarised using mean and SD, and median and interquartile range (Q1-Q3). No statistical test will be performed on baseline characteristics.

4.2 Analysis of the primary outcome

Primary analysis: to evaluate the effect of the intervention on the proportion of encounters for back pain due to a musculoskeletal condition where low-value care was provided, we will use a multi-level regression model, with a random effect for cluster and patient (assuming some patients may have several encounters during the study period), a fixed effect indicating the group assignment of each cluster and a fixed effect of time.
The primary outcome will be analysed using a logistic regression to analyse whether either intervention is superior to a 'no nudge' comparison. Odds Ratio and 95%CI between the treatment groups will be provided.

4.2.1 Main analysis

The primary analysis will be conducted to compare the two interventions against the control groups assuming no interaction between two interventions ("patient nudges" and "clinician nudges"). The comparison will be done for yes to "patient nudges" vs no to "patient nudges" (factor 1), and yes to "clinician nudges" vs no to "clinician nudges" (factor 2). The marginal estimate will be produced for each intervention in this factorial design. The intervention effects will be reported as odds ratios (ORs) with corresponding 95% confidence intervals (CIs), using the control group as the reference. The primary analysis will be based on an unadjusted model with fixed effect of intervention and time (before period vs after period), a random effect of clusters (sites) and an interaction between intervention and time to adjust for before-after effect. The intervention effect

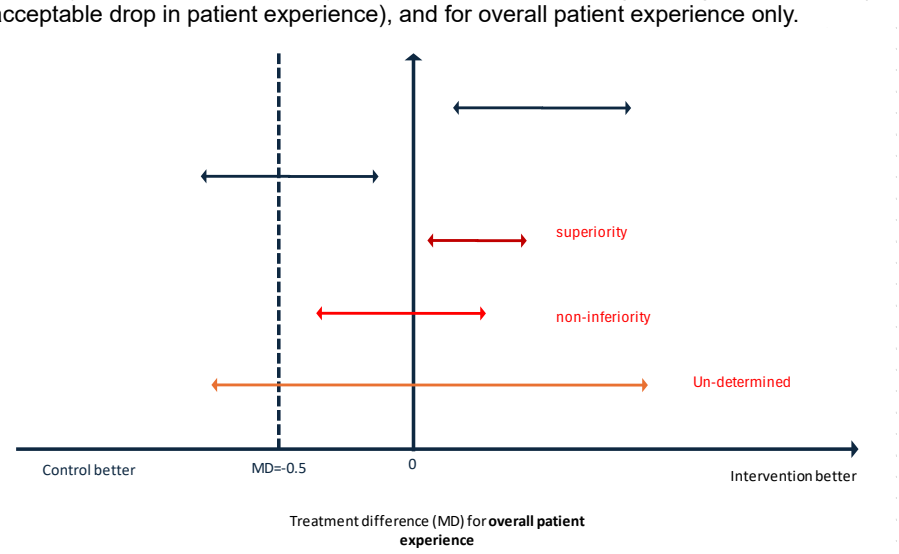
will be estimated for after-period comparison. Sensitivity analysis will be conducted at patient level by removing the duplicate encounters for the same subject, given that there are around 10% of eligible subjects had multiple encounters.
The possible interaction between “patient nudges” and “clinician nudges” will be also tested but only for an exploratory purpose. The 3-way interaction among “patient nudges”, “clinician nudges” and Time, along with their 2-way interactions, will be added to the primary model to explore the interaction between “patient nudges” and “clinician nudges” at after-period. A P-value for the interaction term will be provided as well as descriptive results for the combination of the two interventions, see mock Table 7 for details.

4.3 Analysis of secondary outcomes

All secondary outcome analyses described in this section will be conducted using the intention-to-treat (ITT) primary dataset. Dichotomous outcomes will be compared between groups using generalised estimating equations (GEE) to account for clustering effects. Continuous secondary outcomes will be analysed using the same GEE framework with an appropriate link function. The comparison, between the patient-directed nudge versus the control and the clinician-directed nudge versus the control, will be performed and marginal effect of interventions will be provided with 95%CI.
The interaction between “patient nudges” and “clinician nudges” will be tested by adding an interaction between “patient nudges” and "clinician nudges" in the model. A P-value for the interaction term will be provided as well as descriptive results for the combination of the two interventions.

4.3.1 Patient experience measures

Frequency of overall patient experience measures will be calculated by intervention groups. Chi-square test will be used for categorical variables.
The mean of five items related to ‘Overall assessment of ED Experience’ of the Press Ganey Survey (range 1–5), at 1-week follow-up will be also calculated and compared among intervention groups following the same strategy as primary outcome. Non-inferiority test will be conducted using a margin of 0.5 point (0.5 units is the maximum acceptable drop in patient experience), and for overall patient experience only.



The list of patient experience measures are provided here and in Table 2.

- *Overall how would you rate the care received during your visit to the Emergency Department?*
- *How likely are you to recommend our Emergency Department to others?*
- *Did you see back pain posters while you were in the Emergency Department?*
- *Did you scan a QR code in Emergency Department to receive information about back pain?*
- *How would you rate the efforts of your doctor in the Emergency Department to keep you informed about your treatment?*
- *How would you rate your doctor in the Emergency Department's concern for your comfort while treating you?*

4.3.2 Pain Intensity

The summary scores of pain intensity will be analysed as a continuous variable. Chi-square test will be used for categorical variables. The effect of intervention will be presented as the mean difference and associated 95%CI.

Reference CRF questions:

- *Do you have a history of low back pain?*
- *For how long have you had trouble with low back pain?*
- *How long have you had your current back pain problem?*
- *Please rate your current pain from 0-10.*

4.3.3 Health related quality of life – EQ-5D-5L

Each of the 5 EQ-5D dimensions will be summarised in percentages between intervention groups using Chi-square test. The visual analogous scale (score of 0 to 100) will be analysed using linear regression and the overall health utility EQ-5D-5L score will be calculated using Australia norm and compared between groups in a similar manner to that used for the visual analogous scale.

Reference CRF questions:

- *MOBILITY, PERSONAL CARE, USUAL ACTIVITIES, PAIN / DISCOMFORT, ANXIETY / DEPRESSION*
- *We would like to know how good or bad your health is TODAY.*

4.3.4 Patient participation in decision making (CollaboRATE tool)

Patient participation in decision making will be analysed in both categorical variable and continuous variable.

Calculation of Dichotomous Score (i.e. did SDM happen Yes/no)
Exclude cases where a response to one or more of the collaboRATE questions is missing. Code each encounter as either '1', if the response to all three collaboRATE items was 9, or '0' if the response to any of the three collaboRATE items was less than 9. Then, calculate the percentage of all encounters that were coded as '1'. This number is the collaboRATE Score

Calculation of Mean Score (i.e. extent to which SDM happened)
Exclude cases where a response to one or more of the collaboRATE questions is missing. Calculate the mean of the three collaboRATE responses for each encounter. Then, calculate the mean of all encounters of interest. This number is the collaboRATE Score.

Reference CRF questions:

- *How much effort was made to help you understand your health issues? (0-9)*
- *How much effort was made to listen to the things that matter most to you about your health issues? (0-9)*
- *How much effort was made to include what matters to you in choosing what to do next? (0-9)*
- *CollaboRATE Code: sum of above three questions.*

4.3.5 Reassurance:

Generic reassurance subscale from Consultation-based Reassurance Questionnaire will be analysed as continuous variable.

Reference CRF questions:

- *Tell you that you should not be worried (1-7).*
- *Tell you that everything would be fine (1-7).*
- *Reassure you that they had no serious concerns about your back (1-7).*
- *How reassured do you feel that there is no serious condition causing your back pain? (1-10)*

4.3.6 Referrals to specialist

Referrals to specialist will be analysed as categorical variable using Chi-square test.

Reference CRF questions:

- *Have you been referred to a specialist for the health condition you went to the emergency department for?*
- *Please indicate which specialist the referral was for.*

4.3.7 Intention to seek second opinion

Intention to seek second opinion will be analysed as categorical variables using Chi-square test.

Reference CRF questions:

- *Thinking about experiences you have had with the Emergency Department, how likely or unlikely are you to get a second opinion about your back pain?*
- *Did you see your GP or physiotherapist for your back after attending the emergency department?*

4.3.8 Patient beliefs about imaging and opioids

Patient beliefs questions will be analysed as categorical variables using Chi-square test.

Reference CRF questions:

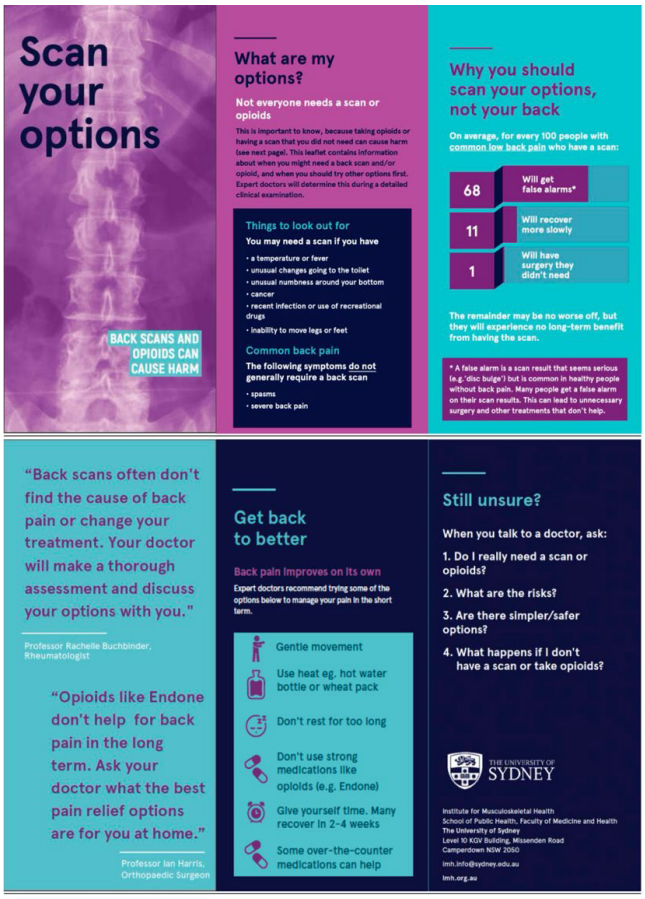
- *Imaging tests (e.g. X-ray, CT or MRI) are necessary to get the best medical care for low back pain*
- *Everyone with low back pain should have spine imaging (e.g. X-ray, CT or MRI)*
- *Opioid medicines are e□ective long term pain relievers for people with low back pain*
- *During the past week, how much did low back pain interfere with your normal work (including both work outside the home and housework)?*

References

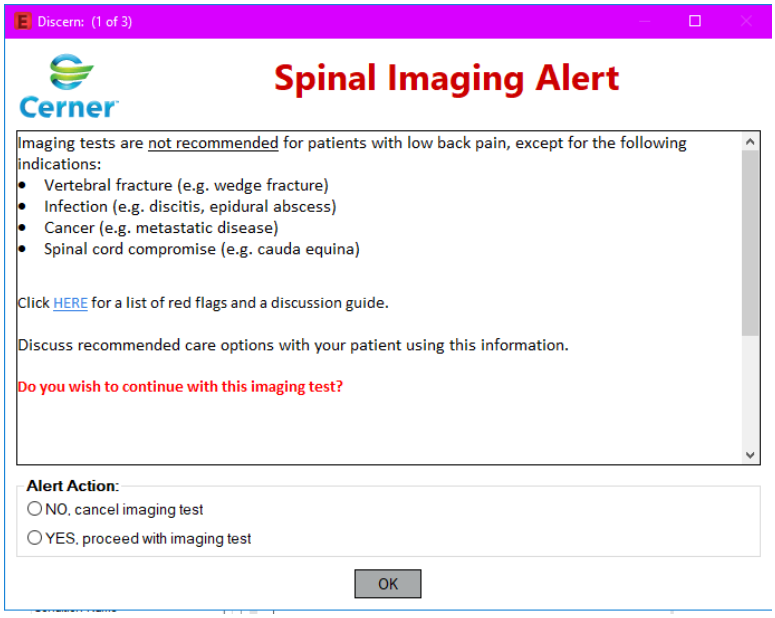
1. Altinger G, Sharma S, Maher CG, Cullen L, McCaffery K, Linder JA, Buchbinder R, Harris IA, Coiera E, Li Q, Howard K, Coggins A, Middleton PM, Gunja N, Ferguson I, Chan T, Tambree K, Varshney A, Traeger AC; NUDG-ED Study Group. Behavioural 'nudging' interventions to reduce low-value care for low back pain in the emergency department (NUDG-ED): protocol for a 2×2 factorial, before-after, cluster randomised trial. BMJ Open. 2024 Mar 28;14(3):e079870. doi: 10.1136/bmjopen-2023-079870. PMID: 38548366; PMCID: PMC10982715.
2. Traeger AC, Machado GC, Bath S, et al. Appropriateness of imaging decisions for low back pain presenting to the emergency Department: a retrospective chart review study. Int J Qual Health Care 2021;33:mzab103.
3. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c332.

eFigures

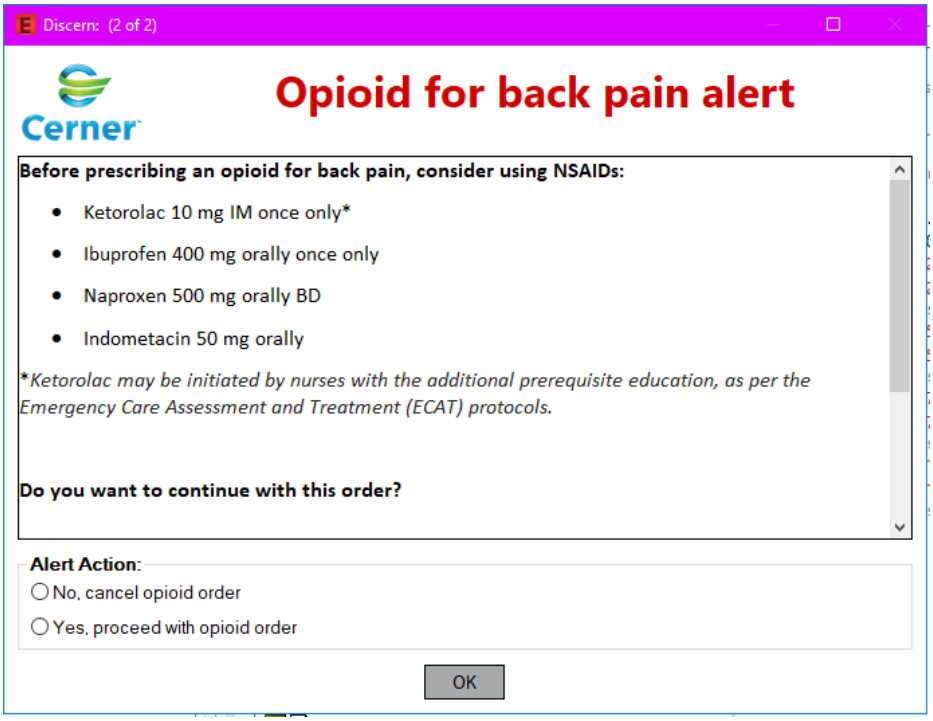
eFigure 1: Patient Nudges - Waiting room information posters



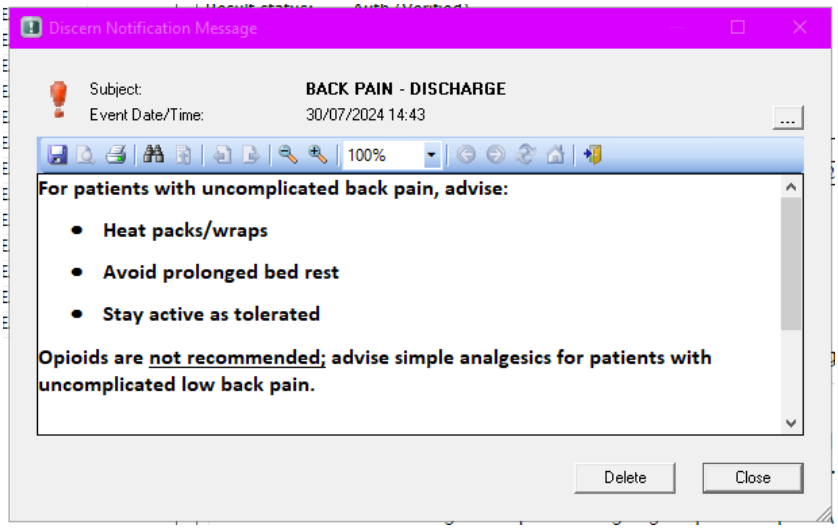
eFigure 2: Patient information brochure



eFigure 3: Clinician Nudge- Imaging alert and linked information



eFigure 4: Clinician Nudge- Opioid for back pain alert



eFigure 5: Clinician Nudge- Discharge alert

eTable 1: Interaction for primary outcome

Before period	**Low Value Care**		**Patient nudge group**	
			Yes	**No**
	Clinician nudge group	**Yes**	163/352 (46.3%)	111/263 (42.2%)
		No	104/322 (32.3%)	132/289 (45.7%)
After period	**Low Value Care**		**Patient nudge group**	
			Yes	**No**
	Clinician nudge group	**Yes**	286/672 (42.6%)	194/545 (35.6%)
		No	218/713 (30.6%)	241/597 (40.4%)
Overall	**Low Value Care**		**Patient nudge group**	
			Yes	**No**
	Clinician nudge group	**Yes**	449/1024 (43.8%)	305/808 (37.7%)
		No	322/1035 (31.1%)	373/886 (42.1%)

P-value for interaction = 0.357

eTable 2

Characteristics of responders and nonresponders to patient-reported outcomes survey		
Characteristic	**No. (%)* of invited patients**	
	Nonresponders *n* = 1051	**Responders *n* = 441**
Sex		
Female	**536 (51.0)**	**238 (54.0)**
Male	**515 (49.0)**	**203 (46.0)**
Age, yr	**46 (34–64)**	**47 (36–60)**
Language spoken at home		
English	**893 (85.0)**	**410 (93.0)**
Other	**158 (15.0)**	**31 (7.0)**
IRSAD		
Advantaged postcode	**631 (60.0)**	**221 (50.1)**
Disadvantaged postcode	**420 (40.0)**	**220 (49.9)**
Note: IRSAD = Index of Relative Socioeconomic Advantage and Disadvantage. ***Unless indicated otherwise.**		