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Exploring the integration of behavioural experiments into eating disorders treatment

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DECLARATION

This dissertation is being presented as part of the requirements for the degree of Master of Occupational Therapy in the Faculty of Health Sciences, University of Sydney, on 28th October 2015.

This work has not been submitted for any form of credit to any other university or institution.

This research project was developed as part of a larger project evaluating a newly established day program for individuals with eating disorders associated with a major metropolitan hospital in Sydney, Australia. Maidei Machina wrote the literature review, carried out the data analysis, and writing of the manuscript with appropriate assistance and supervision.

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Abstract

This dissertation explores the value and usefulness of behavioural experiments in the treatment of eating disorders. The dissertation is presented as two components:

- Section One: A literature review
- Section Two: A journal manuscript

The literature review provides background on the characteristics, aetiology and prevalence of eating disorders, empirical evidence of current treatment approaches, and empirical evidence of the efficacy of behavioural experiments. The review also details the role of maladaptive assumptions and beliefs on the development and maintenance of eating disorders, specifically for the purpose of highlighting the need for further investigation into the treatment potential of behavioural experiments.

The findings of the literature review informed the conceptualization and design of the research study, a qualitative study with an exploratory approach. Qualitative data in the form of Behavioural Experiment – Practical Food Group record sheets were analysed to investigate the value and usefulness of behavioural experiments in the treatment of eating disorders.

The second section of this dissertation is a journal manuscript of the research study. It contains the findings of the study and the clinical implications of this research. This research manuscript will be submitted to the Journal of Eating Disorders.

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Section One: Literature Review

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1. INTRODUCTION

1.1 Background to the Topic

Eating disorders comprise of a range of chronic, and potentially life threatening, mental illnesses characterized by abnormal and persistently disturbed exercise, eating and eating-related behaviours (National Eating Disorders Collaboration [NEDC], 2012). The pervasive and adverse impact of these disorders on the physical, emotional and psychological well-being of an individual often result in decreased quality of life. Commonly misconstrued as a ‘lifestyle choice’ spurred by the relentless pursuit of vanity and attention, individuals with disordered eating often harbour negative and unconditional self-beliefs, struggle with feelings of low self-esteem, worthlessness and shame (Gillberg, Rastam, Wentz & Gillberg, 2007). These patterns of dysfunctional thinking inadvertently serve to perpetuate the disorder, and further increase the risk of social isolation, interpersonal conflicts, physical harm and reduced engagement in valued everyday occupations (American Psychiatric Association, 2000). As such, deeply entrenched core dysfunctional assumptions and beliefs have long been hypothesized as being key contributing factors to the development and maintenance of eating disorders (Cooper, Todd & Wells, 2004).

Indeed, the call for maladaptive cognitions to be an ‘explicit target *for* intervention’ has an extensive history and was first suggested by Beck & Emery (1979). As a result, cognitive behavioural therapies (CBT), in conjunction with pharmacological treatments and nutritional interventions, have been frequently used in the treatment of eating disorders. This comprehensive and holistic approach to treatment has met with some success. However, relapse, re-hospitalisation, and mortality rates on individuals with severe eating disorders remain frustratingly high (Pike, Walsh, Vitousek, Wilson & Bauer, 2003; Franco, 2010). This may suggest that current advancements in treatment, and their implementation, have not translated into improved care (Nishizono-Maher, Escobar-Koch Ringwood, Banker, van Furth & Schmidt, 2011). As such, further empirical investigations to better understand the aetiology and processes underpinning the development and maintenance of maladaptive beliefs may have important implications for treatment development (Woolrich, Cooper & Turner, 2006). In addition, research into the advancement and refinement of current treatment approaches may be necessary.

One such treatment that is commonly recommended for implementation in the treatment of a wide range of psychopathologies, but has been sparsely researched to assess its value and treatment effectiveness of eating disorders are behavioural experiments. Designed for

implementation as structured experiential activities, behavioural experiments are used to test the validity of beliefs and/or construct new rational beliefs (Bennett-Levy et al., 2004). Initial evidence of the value and effectiveness of behavioural experiments in the treatment of depression, anxiety related disorders, obsessive compulsive disorder and phobias have been shown in several studies (Salkovskis, Clark, Hackmann, Wells & Gelder 1999; Kim, 2005) and comprehensively evaluated in a systematic review (McMillan & Lee, 2010). Yet, this is surprisingly little research investigating the use and efficacy of behavioural experiments in the treatment of eating disorders. Shared similarities in clinical symptomologies, alongside the phenomena of fostering dysfunctional beliefs, between eating disorder and previously mentioned psychopathologies suggests that there may be beneficial overlap in treatment approaches (Barlow & Durand, 2005; Fairburn, 2008a).

This study therefore proposes to explore the usefulness of behavioural experiments in altering the maladaptive beliefs of individuals with eating disorders; whilst providing further insight into the typical content of maladaptive beliefs frequently targeted for testing.

1.2 Theoretical Framework

The Person Environment Occupation Performance Model (PEOP) (Baum & Christiansen, 2005) was used to guide the conceptualization, design and aims of this study. As a client-centred occupational therapy practice model, emphasis is placed on improving an individual's abilities to engage in everyday activities that are meaningful and purposeful to them, and in the world around them (Smith & Hudson, 2012). Unique to this model, is its focus on the ability of an individual's 'person factors' (i.e. cognitive abilities, psychological state of mind, personal experiences) to serve as barriers to one's level of occupational participation (engagement in a task) and optimal occupational performance (the 'doing' of a task). In the context of eating disorders, this intimate and interdependent interaction between an individual's 'person', 'environmental' and 'occupational' factors is demonstrated by the effects of abnormal 'person factors' (i.e. maladaptive cognitions and beliefs) on an individual's social and occupational participation. Engagement in behavioural experiments allows people the opportunity to gain the skills they need to manage their anxieties and alter maladaptive beliefs in a 'real world' setting. In doing so, the cognitive and behavioural barriers to participation in valued occupations (i.e. self-care tasks, formal employment) and social interactions are overcome.

1.3 Search Strategy

A rigorous and methodical search of the databases: PsycINFO, Medline, Web of Science Core Collections, CINAHL, AMED, Medline and Scopus was conducted between March 2015 and October 2015 in order to identify any, and all, relevant literature that was included in this review. Nine search terms were chosen and used for this purpose. The search terms included: behavioural experiments, cognitive behavioural therapy, maladaptive cognitions, dysfunctional beliefs, core beliefs, eating disorders, Anorexia Nervosa, Bulimia Nervosa, Binge Eating Disorder. In order to ensure that all relevant articles and publications were located and included in this study, the search was not limited to a specific timeframe. The search was however, limited to English language publications. The reference lists of the identified articles were reviewed in order to increase the likelihood of locating any additional publications that may have been missed in the database search. The relevance of each retrieved article or publication was assessed by reading the title and abstract; and when necessary, the entire paper.

A Google scholar search was undertaken to locate any other relevant literature or published conference and seminar reports. A Google search of both Australian and international government health websites, university websites and general internet sites was also undertaken for the purposes of identifying other relevant documents and information.

2. EATING DISORDERS

Eating disorders have the highest morbidity and mortality rates of any psychiatric diagnosis. Factors that contribute to the onset and development of eating disorders are numerous, often varied, and complex. Known potential risk factors include: socio-cultural influences (i.e. cultural pressure to be thin) (Button & Warren, 2001), psychosocial factors (i.e. traumatic events) (Neumark-Sztainer, Story, Hannan, Beuhring & Resnick, 2000), psychological factors (i.e. perfectionism, low self-esteem) (Stice, 2002); alongside genetic and biological factors (i.e. genetic predisposition) (Yilmaz, Hardaway & Bulik, 2015). This often results in people with disordered eating experiencing changes or reductions in emotional, mental, cognitive and physical functioning.

2.1 Characteristics and Aetiology

Anorexia Nervosa (AN)

- A disorder characterized by dramatic weight loss that is primarily the result of restrictive food intake, excessive exercise, induced vomiting and/or the misuse of diuretics or laxatives.
- Individuals with AN frequently endorse maladaptive assumptions and beliefs that include: negative beliefs about weight and shape (i.e. ‘I have too much fat on my body’), negative self-beliefs (i.e. ‘I ought to be thin’), negative core beliefs (i.e. ‘I am worthless’), and dysfunctional biases regarding food and eating (i.e. ‘Chocolate is nothing bad fat and carbs. I shouldn’t eat it’) (Garner & Gerborg, 2004).

Bulimia Nervosa (BN)

- A disorder characterized by recurrent binge eating episodes followed by compensatory behaviours to ‘un-do’ the act of eating, such as self-induced vomiting or misuse of diuretics.
- Individuals with BN frequently endorse thoughts of having no control, negative beliefs about body shape and weight, beliefs about food in regards to weight gain or core beliefs (i.e. ‘If I eat pizza, I will get fat’; ‘If I eat, then I’m a failure’), and permissive thoughts that perpetuate bingeing behaviours (i.e ‘I might as well carry on eating now that I have started’) (Cooper, Wells & Todd, 2004).

Binge Eating Disorder (BED)

- A disorder characterized by recurrent episodes of binge eating without subsequent compensatory behaviours.
- Individuals with BED frequently endorse thoughts of having no control, and strong concerns about body shape and weight (Iacovino, Gredysa, Altman & Wilfley, 2012).

Eating Disorders Not Otherwise Specified (EDNOS)

- A diagnosis given to individuals who do not meet the diagnostic criteria of AN, BN. Individuals often present with extreme fear of weight gain, disturbed eating habits and distorted body image perceptions.
- Individuals with EDNOS often endorse thoughts and maladaptive beliefs similar to those of individuals with AN or BN (NEDC, 2012).

2.2 Onset

Research has suggested that the age of onset for eating disorders has decreased over in recent generations (Favaro, Caregaro, Tenconi, Besolle & Santanastaso, 2009). Studies have also

shown that the onset of disordered eating tends to be later in males than in females (Carlat, Camargo & Herzog, 1997).

Anorexia Nervosa

- The average age of onset for AN in males and females was 18.1 years and 17.4 years of age, respectively;
- The incidence rates of AN was observed to have 2 peaks: one around 14.5 years and another around 18 years of age (Favaro, Caregaro, Tenconi, Besolle & Santanastaso, 2009).

Bulimia Nervosa

- The age of onset tends to be 18-26 years for males and 16-18 years for females;
- The incidence rates for BN was shown to peak among females between 20-24 years of age (Favaro, Caregaro, Tenconi, Besolle & Santanastaso, 2009)

Binge Eating Disorder

The onset of BED varies depending on what began first, dieting or binge eating behaviours.

- Dieting Firsts: The age of onset tends to be around 25 years of age;
- Binge Eating First: The age of onset tends to be around 12 years of age;
- Whether an individual dieted or binged first was not shown to influence eating patterns, symptoms of psychological distress, or degree of weight gain in one case more than another (Spurrell, Wilfley, Tanofsky & Brownell, 1996).

Eating Disorders Not Otherwise Specified

Existing data on the age of onset for EDNOS remains. This has been attributed in part to the lack of agreement in diagnostic criteria (Wade, Bergin, Tiggemann, Bulik & Fairburn, 2006).

2.3 Long-term course

The short-term or long-term course of eating disorders vary greatly. In some cases, an eating disorder is short-lived and either self-resolves or requires only brief intervention. In other cases, the disorder is deeply entrenched and requires prolonged, intensive intervention. Lastly, in approximately 6-20% of cases, patients prove to be treatment refractory as the disorder proves to be unremitting (Fairburn & Harrison, 2003).

Several prospective studies on the natural course and treatment outcomes of BN and EDNOS have shown that remission is observed in approximately 74% of BN cases, and 83% of EDNOS cases (Ben-Tovim et al., 2001; Grilo et al., 2007). Within those same populations, the incidence of relapse were 47% for BN and 42% for EDNOS (Milos, Spindler, Schnyder & Maidei Machina 440115766 – University of Sydney
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Fairburn, 2005). In the case of AN, the rate of recovery is estimated at 33%, with one-third of fully recovered individuals subsequently relapsing (Herzog et al., 1999). Unique to the course of AN are the low rates of full recovery and high rates of partial recovery. In the case of BED, a study by Fairburn, Cooper, Doll, Norman & O'Conner (2000) reported that remission was observed in 83% of BED cases, with the rate of relapse continually decreasing over the course of 5 years from 10% to 6%.

2.4 Prevalence and burden of illness

The incidence of eating disorders in the Australian population is estimated 1 in 20 (NEDC, 2012), with 4% of the population being affected to clinically significant levels (Deloitte Access Economics, 2012). Translated, this means approximately 913,000 Australians have an eating disorder. Of these people, an estimated 3% have Anorexia Nervosa (AN), 12% have Bulimia Nervosa (BN), 47% have Binge Eating Disorder (BED), and 38% have Eating Disorders Not Otherwise Specified (EDNOS) (Deloitte Access Economics, 2012). Evidence suggests that, as the rate of the Australian population continues to rise, the overall prevalence of eating disorders may also increase (Hay, Mond, Buttner & Darby, 2008). Inadvertently, the socioeconomic impact of eating disorders is therefore also projected to rise. The *Paying the Price* report published in 2012 estimated the cost of eating disorders as \$52.6 billion, with health system expenditures estimated as 99.9 million (Deloitte Access Economics, 2012). Indeed, the burden of disease is significant. Further necessitating the need to allocate additional resources to the effective treatment of individuals with eating disorders.

3. CURRENT TREATMENT METHODS

3.1 Pharmacological Treatment

Although pharmacotherapy is not recommended as a first choice treatment option for eating disorders, the co-occurrence and comorbidity of eating disorders with other medical and/or psychiatric illnesses commonplace (Fairburn & Harrison, 2003; Kay, Bulik, Thornton, Barbarich & Masters, 2004; Milano, De Rosa, Milano, Riccio, Sanseverino & Capasso, 2013). As a result, pharmacotherapies have often been administered for the purposes of ensuring the treatment and management of comorbid conditions that may serve to exacerbate and/or perpetuate eating disorder symptoms. It is important to note however, that in some instances, medications intended for the treatment of comorbid conditions have resulted in the alleviation of eating disorder symptoms (NICE, 2004). To illustrate, a randomized controlled trial by Guerdjiko et al., (2012) demonstrated the efficacy of the antidepressant duloxetine on

reducing body weight and the frequency of binge-eating episodes in 40 patients with BED. The hypothesized mechanism of action of duloxetine in reducing body weight and the incidence of binge eating is primarily biomechanical, as the medication works to modify internal signals that control feelings of hunger and satiety (Milano, De Rosa, Milano, Riccio, Sanseverino & Capasso, 2013). Additional evidence suggests that the treatment of depressive symptoms may result in the alleviation of symptoms and the correction of disturbed behaviours associated with BED (Guerdjiko et al., 2012). Anti-depressants have also been shown to contribute to the cessation of binge-purge episodes for BN (NICE, 2004). For AN, evidence of the influence of pharmacotherapy on the core symptoms of the disorder has been dismal (NICE, 2004).

Broadly, evidence for the successful treatment of eating disorders by pharmacotherapy alone is weak to moderate (Bulik, Berkman, Brownley, Sedway & Lohr, 2007; Hay & Claudino, 2012). The treatment of eating disorder requires the implementation of multiple intervention strategies that target both the physical (i.e reversal of detrimental consequences of malnutrition), emotional (i.e. mood disturbance), and psychological (i.e. changing or modifying maladaptive beliefs) aspects of the disorder.

3.2 Nutrition Interventions

Nutritional counselling, in addition to medical nutrition therapy and nutrition education provided by registered dietitians are well-established strategies for treating individuals with eating disorders (Beumont & Touyz, 1995; American Dietetic Association, 2006). More specifically, the management of eating disorders through nutrition rehabilitation has been shown to be useful in encouraging weight restoration, normalizing food intake and rectifying the negative physiological effects of malnutrition (Waisberg & Woods, 2002; Rios, 2012). Further, nutrition education and counselling have been found to reduce irrational fears, maladaptive beliefs and anxieties related to eating, weight gain and body shape (American Psychiatric Association, 2000). Nutrition counselling has also been found to increase self-awareness, knowledge of food selection, meal preparation and assist in the elimination of distorted eating patterns (Latner & Wilson, 2000; King & Klawitter, 2007).

The value of nutrition interventions is undisputed. However, there is limited outcomes related research to substantiate the long-term efficacy of these treatment strategies in isolation. As a result, nutrition and pharmacological treatment strategies are often integrated into multimodal

rehabilitation treatment packages with a strong psychotherapy focus (Brambilla, Driasci, Peirone & Brunetta, 1995; Waisberg & Woods, 2002). As part of a comprehensive treatment package, nutrition rehabilitation has proven to be beneficial in the treatment of eating disorders.

3.3 Cognitive Behavioural Therapy

Cognitive-behavioural Therapy (CBT) is the most intensively researched and empirically supported form of psychotherapy (American Psychiatric Association, 2000). It has been shown to be a fast-acting, highly individualized form of treatment that is capable of producing clinically significant levels of treatment effectiveness in changing or modifying the maladaptive cognitions and behaviours patterns that are associated with a wide range of emotional, cognitive and behavioural psychopathologies (Fairburn et al., 2009; Hofmann, Asnaani, Vonk, Sawyer & Fang, 2012). Based on the cognitive model by proposed by Fairburn (1997), the defining feature of this treatment approach is its unique focus on the interactions between a person's thoughts, feelings and behaviours that combine to either positively or negatively influence one's quality of life (Fairburn, 1997; Blagys & Hilsenroth, 2002). The cognitive and behaviourally based treatment techniques that are employed during CBT, aim to alter an individual's negative thoughts about the self, specific situations or the world, that often result in self-destructive feelings and behaviours. This has resulted in CBT being the most recommended form of psychotherapy, as the 'core' of psychopathology is often cognitive in nature (Fairburn, 2008*b*).

CBT is widely regarded at the gold standard form of treatment for BN (Walsh et al., 1997; Murphy, Straebler, Cooper & Fairburn, 2010). Past reviews of the literature on the treatment effectiveness of CBT on BN have shown that an estimated 40%-50% of patients recover from the disorder (Keel & Mitchell, 1997; Thompson, 2002), as was evidenced by abstinence from, or significant reductions in, binge-eating and purgative behaviours. Notwithstanding being helpful to many people, CBT does have limits to its effectiveness. Meta-analyses have found that despite the significant and rapid therapeutic effects of CBT, only 29% of individuals with BN remain recovered after 12 months (Fairburn, Cooper & Shafran, 2003). Further, evidence on the efficacy of CBT in reducing or modifying maladaptive beliefs about shape and weight is conflicting (Anderson & Maloney, 2001; Hay, Bacaltchuk, Stefano & Kashyap, 2009), as results are highly dependent on the outcome measure used.

There is evidence to suggest that CBT is also effective in the treatment of BED and EDNOS; albeit there is less research on the treatment of the latter (NICE, 2004; Fairburn et al., 2009; Murphy, Straebler, Cooper & Fairburn, 2010). The growing body of literature has shown that a form of CBT similar to that used to treat BN has been effective in reducing the frequency of binge-eating, but with minimal effect on body weight (Brownley, Berkman & Sedway, 2007). Significantly less outcomes related research is available regarding the efficacy of CBT on AN. As far as evidence goes, a systematic review by Galsworthy-Francis and Allan (2014) concluded that, although CBT appeared to lead to improvements in eating disorder symptoms for AN, CBT did not demonstrate superiority over comparison treatments.

Given the previously mentioned caveats, CBT is continually evolving, and an 'enhanced' form of cognitive behavioural therapy (CBT-E or Transdiagnostic CBT for Eating Disorders), has developed based on the transdiagnostic cognitive model by Fairburn and colleagues (Fairburn et al., 2008). CBT-E differs from traditional CBT in that, it takes into account the behavioural and psychological mechanisms that contribute to the development and maintenance of disordered eating, such as mood intolerance, core low self-esteem, clinical perfectionism and interpersonal difficulties (Fairburn et al., 2008; Cooper & Fairburn, 2011). Although preliminary evidence suggests that this 'enhanced' version of CBT treatment is more effective than traditional CBT in the treatment of BN and BED (Fairburn et al., 2009), additional research is still required in order to refine interventions and assess the efficacy of CBT-E on AN and EDNOS. To give an example, of 154 patients diagnosed with an eating disorder, 51% of the sample had a level of eating disorder features less than one standard deviation about the community mean.

While the advancements in the formulation of new and more effective forms of CBT are admirable, CBT is a form of psychotherapy with a number of intervention techniques embedded within it; namely cognitive reconstruction, exposure therapy, cognitive emotional behavioural therapy, behavioural experiments etc. All of which are not as equally efficacious in the treatment of eating disorders and other psychopathologies (Longmore & Worrell, 2007). By way of evidence, Hayes (2004) highlighted that, an analysis of outcome literature has shown that cognitive interventions associated with CBT did not provide added value to therapy. Further, Orsillo, Roemer, Lerner & Tull (2004) noted that, the active ingredient that generates change in CBT remains unknown. Primarily due to the very nature of CBT as a form of psychotherapy that houses multiple intervention strategies. This has resulted in calls

by researchers and clinicians for more in depth analysis of the efficacy of individual components of CBT (Longmore & Worrell, 2007).

4. BEHAVIOURAL EXPERIMENTS

The importance of cognition in the development and maintenance of eating disorders is well documented, as individuals with disordered eating are known to judge themselves largely in terms of their body shape, weight, eating habits, and their ability to control these aspects of their lives (Fairburn, Cooper & Shafran, 2003; Cooper, Todd & Wells, 2004). Therefore, the identification and subsequent changing or modifying of these maladaptive assumptions and beliefs, is hypothesized to be an essential component to the successful treatment of eating disorders (Cooper, Todd & Wells, 2004). One way of successfully achieving these aims may be in the implementation of behavioural experiments.

4.1 What are behavioural experiments?

Behavioural experiments combine the cognitive (thinking) and behavioural (doing) aspects of traditional CBT, and are considered as having a powerful influence in enabling therapeutic change (Bennett-Levy et al., 2004). Implemented as structured, experiential activities, behavioural experiments are designed for the primary purposes of testing “the validity of the patients’ existing beliefs about themselves, others and the world; construct and/or test new, more adaptive beliefs; and contribute to the development and verification of the cognitive formulation” (Bennett-Levy et al., 2004, p. 8). Simply put, behavioural experiments are hypothesis-testing experiential activities in which beliefs or key cognitions are challenged in real-life situations, and subsequently reflected upon for the purposes of either validating or disproving them. This unique opportunity to challenge beliefs in a real-world setting reduces the vulnerability of people to negative thoughts, in addition to promoting the formulation and adoption of new, more realistic beliefs.

4.2 Theoretical Perspective

Part of the clinical relevance and value of behavioural experiments is obtained from the field of adult education, as the value of personal experience (doing) has always been deemed as an essential component for effective learning (Kolb 1984). As demonstrated by the Lewin/Kolb four stage experiential learning model (Kolb 1984), effective learning occurs through a series of: Abstract Conceptualisation - Active Experimentation - Concrete Experience - Reflective Observation, cycles. Within the context of behavioural experiments, typically, a patient is

encouraged to identify a belief for testing and also predict what will happen (Abstract Conceptualisation); the patient then goes and engages in the experiential activity (Active Experimentation); afterwards, documents the outcome (Concrete Experience); then lastly, the patients reflects upon what occurred for the purposes of either validating or disproving the previously identified belief (Reflective Observation). This opportunity to, engage, not only in an experiential activity, but in the process of planning and reflecting on one's experience, is the essence of what makes of behavioural experiments effective (Bennett-Levy, 2004).

4.3 Empirical Evidence

Several studies and a systematic review have provided preliminary evidence that behavioural experiments are an efficacious form of treatment for various psychopathologies which include: anxiety related disorders, phobias and obsessive compulsive disorder (Salkovskis, 1999; Kim, 2005; McMillan & Lee, 2010). For example, the study by Salkovskis et al.,(1999) used a clinical sample of 18 patients with agoraphobia to investigate whether decreased engagement in safety-seeking behaviours (behaviour change) was associated with disconfirmation of threat beliefs (maladaptive beliefs). The study compared two treatment conditions: one in which patients received treatment in a series of 15 minute behavioural experiments during which patients refrained from engaging in safety behaviours thus challenging threat beliefs; and another in which patients received 15 minutes of traditional exposure treatment without explicitly seeking to challenge threat beliefs. The results from this study revealed that cognitively delivered exposure treatments (behavioural experiments), during which patients sought to decrease engagement in safety behaviours, were associated with significantly greater belief change and reductions of feared situations.

Further, a systematic review by McMillan and Lee (2010) evaluated 14 independent studies in which the treatment effectiveness of behavioural experiments in lowering anxiety and the believability of maladaptive beliefs was compared to that of exposure therapy alone. The findings revealed that behavioural experiments were more effective in, not only lowering anxiety and the believability of maladaptive beliefs, but in some cases, also decreased engagement in abnormal behaviours. The reviewers however, stress the importance of not overstating the findings of this review for several reasons. Firstly, the experiential conditions in which cognitions were tested varied significantly between studies (i.e. whether therapists were present during experiments, whether participants were presented with the same exposure situations). Secondly, it remained unclear if reflective practice was encouraged for the

purposes of reinforcing learning. Lastly, although behavioural experiments were frequently shown to be more effective than exposure therapy alone in lowering anxiety and altering maladaptive cognitions, results across studies were not consistent.

Using Salkvoskis and colleagues work, in conjunction with that of McMillan and Lee, it can be tentatively determined that, preliminary empirical research evidence supports the notion that behavioural experiments are effective in altering maladaptive beliefs and elicit behavioural change. Nonetheless, additional research must be undertaken taking several factors into consideration. Firstly, additional research must be conducted using larger sample sizes, as most studies had sample sizes of less than 20. Secondly, experimental conditions that meet the criteria for would be considered an adequately designed behavioural experiment. For a behavioural experiment to be considered as having been ‘adequately-designed’, therapists may want to ensure that all planned experiential activities are carried out for the purposes of testing a specific belief, alongside ensuring that experiments occur in accordance with the Kolb/Lewin experiential learning circle; as enduring change is unlikely to occur unless each step in the process is undertaken.

4.4 Behavioural experiments and eating disorders

The commonalities in symptomatology, in addition to patterns of comorbidity between eating disorders and other psychopathologies (i.e. anxiety related disorders, phobias, obsessive compulsive disorder) (Bulik, 1995; Swinbourne & Touyz, 2007), may suggest that there could be similarities in treatment responsiveness to behavioural experiments.

For example, individuals with eating disorders frequently endorse social fears of eating in public, which are akin to social phobias experienced by individuals with anxiety disorders. Further, obsessionality and ritualistic behaviours are common between individuals with disordered eating (i.e: obsessive thoughts about food, compulsively checking for body fat) and individuals with obsessive compulsive disorder (i.e: obsessive thoughts about contamination, compulsively cleaning and washing). Nevertheless, a review of the literature revealed a lack of research on the efficacy of behavioural experiments in the treatment of eating disorders.

Behavioural experiments are often conducted as a component of multimodal treatment programs that employ a combination of psychotherapy, nutrition and pharmacological treatments. For this reason, the isolated treatment effectiveness of behavioural experiments in

eating disorders has not be extensively researched. The potential to improve the permanence of recovery of individuals with eating disorders by way of changing or modifying maladaptive beliefs necessitates the need to investigate the value and usefulness of behavioural experiments in treating eating disorders (Waller et al., 2007).

5. CONCLUSION

Investigations into the efficacy of behavioural experiments are still at an early stage compared to research of traditional CBT or other CBT intervention techniques. Further, to our knowledge, little or no research has been conducted to investigate the effectiveness of behavioural experiments in changing or modifying the maladaptive cognitions of individuals with disordered eating. Indeed, exploratory and empirical studies are required to fill this gap in knowledge.

Therefore, this study will focus on providing preliminary evidence of the value and usefulness of behavioural experiments in validating or disproving maladaptive beliefs and assumptions of individuals with eating disorders.

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SECTION 2: JOURNAL MANUSCRIPT

Title Page

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Exploring the integration of behavioural experiments into eating disorders treatment

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Abstract

Background: Relapse and re-hospitalization rates of individuals with severe eating disorders remain frustratingly high. This may be the result of the failure of current treatment methods to produce long-term sustainable cognitive and behavioural changes in individuals with eating disorders.

Aims: This qualitative study aims to: 1) provide insight into the typical content of maladaptive beliefs, and 2) explore the potential usefulness of behavioural experiments in validating or disproving the maladaptive beliefs of individuals with eating disorders.

Methods: The authors analysed pre-collected Behavioural Experiment - Practical Food Group record sheets of 52 female participants aged 18-65 years receiving treatment from a newly-established day program for individuals with eating disorders. Data was manually coded and analysed for themes to determine the typical content of maladaptive beliefs. The validation or disproving of maladaptive beliefs was analysed using a behavioural experiment feedback loop.

Results: Ten themes emerged from the data. These included beliefs about: 1) forbidden foods, 2) weight, 3) portion sizes, 4) negative self-beliefs, 5) decision making, 6) negative emotions, 7) shopping and eating in public, 8) compensatory behaviours, 9) need for control, and 10) cooking skills. Almost 70% of the behavioural experiment feedback loops were deemed to be 'broken', as most participants did not fully reflect upon their maladaptive beliefs.

Conclusions: The lack of engagement in self-reflection following an experiential activity resulted in numerous missed opportunities for patients to validate or disprove their maladaptive beliefs. This was hypothesised to be a direct result of the multiplicity and diversity of the maladaptive beliefs of individuals with eating disorders, alongside the incompatibility of the traditional behavioural experiment record sheet for use in the context of group-based therapy.

Keywords: Behavioural Experiments; Eating Disorders; Maladaptive Beliefs; Qualitative

Introduction

Eating disorders (EDs) are typically chronic mental illnesses with significantly high morbidity and mortality rates, affecting 9% of the Australian population [1]. Despite years of research efforts and the administration of evidence-based treatments, relapse and re-hospitalization rates of individuals with severe EDs remain as high as 30 - 50% within two years of hospital discharge, or the cessation of outpatient care [2][3]. The identification of determinant factors that contribute to relapse of EDs have therefore been the focus of significant recent research efforts. One hypothesized causal mechanism attributed to patients remaining treatment refractory, is the inability of current treatment methods to alter the maladaptive beliefs and assumptions associated with disordered eating [4]. As a result, psychological therapies such as cognitive behaviour therapy (CBT) have been widely recommended as important components of interventions for EDs [5][6]. Maladaptive cognitions, assumptions and beliefs are recommended to be ‘an explicit target for intervention’ [7]-[9].

One of the most commonly used techniques in CBT is Behavioural Experiments (BEs) [10]. BEs are hypothesis-testing experiential activities designed collaboratively by therapists and patients, during which a cognition is tested through a real-life experience [11]. BEs share many functional similarities with exposure therapy, but are explicitly framed as a test to validate or disprove key beliefs or cognitions so as to encourage intrinsic learning and behavioural change [10][11]. Typically, patients are asked to identify a belief to test during an experiment; then predict the outcome of the experiment; they then engage in the experiment; and subsequently reflect on the experience and state what actually eventuated. Evidence of the value and effectiveness of BEs in the treatment of psychopathologies such as obsessive compulsive disorder (OCD), anxiety disorders, post-traumatic stress disorder, and social phobias has been illustrated in several studies and a systematic review [12]-[15]. More specifically, the systematic review compared the efficacy of BEs relative to another commonly prescribed CBT technique, exposure, on their ability to alter the maladaptive beliefs of clients with OCD, panic disorder and social phobias [15]. Fourteen independent studies were reviewed and the findings supported the notion that BEs were more effective than exposure alone in altering maladaptive cognitions and behaviours [15]. The successful use of BEs in altering the maladaptive beliefs and behaviours of individuals with panic disorder, social phobias and OCD begs the question of whether BEs may be a successful intervention strategy in the treatment of EDs.

The importance of distorted cognitions in the maintenance of psychiatric problems in both EDs and anxiety related disorders is well documented as being at the ‘core’ of psychopathology [16]-[18]. Many individuals with EDs experience similar clinical symptomologies and maladaptive cognitive processes as those described in OCD, phobias and anxiety related disorders. These include fears or maladaptive beliefs related to food and eating situations, abnormal eating rituals, alongside engagement in abnormal safety behaviours, avoidance behaviours, or compensatory actions to manage fears and anxieties [19][20]. To illustrate, in social anxiety, intense self-focus gives rise to a wide range of thoughts such as: ‘Everyone will be staring at me’, ‘I sound stupid’. Such thoughts are akin to those found in EDs such as: ‘Everyone will be watching me eat and judge me’, ‘I can’t go shopping without purchasing binge foods’. Further, obsessive thoughts and ritualistic behaviours are common in both individuals who experience OCD (i.e. obsessive thoughts about germs or bacteria, and compulsive behaviours such as repeated hand washing) and individuals with EDs (i.e. obsessive thoughts about food and compulsive behaviours such as excessive time spent exercising). In short, patients with EDs often manifest both behaviours and beliefs that are akin to OCD and anxiety related psychopathologies. Although there may exist important difference between EDs and these psychopathologies, the shared clinical phenomena of maladaptive beliefs and assumptions, may suggest that there could be valuable overlap in treatment strategies; namely BEs.

BEs are considered to be amongst the most powerful and most commonly used treatment methods for bringing out belief and behavioural changes in individuals with a wide range of psychopathologies [11]. However, there is surprisingly little research on the clinical implementation, value, and efficacy of BEs in the treatment of disordered eating [10][21]. Most outcomes related research of CBT in the treatment of EDs evaluates the effectiveness of whole CBT packages, with little to no research having been conducted on the value and efficacy of specific CBT techniques [10]. This has resulted in there being sparsely any research on the value of BEs in the treatment of EDs.

The current research therefore aimed to explore the usefulness of BEs in validating or disproving the maladaptive beliefs of individuals with EDs. Alongside providing further insight into the typical content of maladaptive beliefs frequently targeted for change. This qualitative study was conducted using an exploratory approach. The exploratory aspect involves an attempt to gain insights and understanding of the usefulness of BEs in the

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treatment of EDs. An important argument for this approach is that it allows for the generation of new ideas, the refinement of already identified problems, and the development of tentative theories and more precise future research questions.

Method

This study formed part of a larger project evaluating a newly-established day program for individuals with EDs. The program was associated with a major metropolitan hospital in Sydney, Australia. Admission criteria for the program were: 1) primary diagnosis of Anorexia Nervosa, Bulimia Nervosa, Binge Eating Disorder or Eating Disorder Not Otherwise Specified; 2) aged over 18 years of age; and 3) BMI > 16. Individuals could self-refer to the program or be referred by other specialist eating disorder treatment services, general practitioners or other health-care providers.

At the point of admission, individuals were given information about the research project and, if they were willing to participate, provided written informed consent to the research coordinator. The research project, including the use of participant medical records for research and program evaluation purposes, was approved by the hospital's Human Research Ethics Committee.

Use of Behavioural Experiments in the program

Participants attended the Day Program four days per week. BEs were conducted twice per week as part of a comprehensive, multidisciplinary treatment program. Structured as hypothesis-testing experiments, the primary purpose of these experiments was to help “test the validity of the patients’ existing beliefs about themselves, others and the world” [11]. This intervention consisted of planned group-based experiential activities in the form of Practical Food Groups (PFGs). PFGs took the form of meal preparation and cooking tasks, or “dining out groups” in which participants ate out at local cafes and restaurants. PFGs were structured to provide the opportunity for participants to test their beliefs about food and eating. The outcomes of these experiments would serve to either reinforce or disprove participants’ maladaptive beliefs.

The Behavioural Experiment sessions began by establishing what experiential PFG activity would be attempted by participants that day. Participants then completed the first section of a Behavioural Experiments – Practical Food Group (BE-PFG) record sheet that consisted of primarily open-ended anticipatory questions such as: “**Target belief** - what is your belief about what you are attempting? Strength of target belief (0-100%)”, and

“Prediction - what you predict will happen either in the situation or afterwards. Strength of prediction (0-100%)”. Participants also responded to questions regarding what alternative outcomes may eventuate, and what safety behaviours they may engage in during the experiment. The chosen group-based experiential activity was then conducted under the supervision of an occupational therapist and/or dietitian.

After completing the PFG, participants were asked to complete the final section of the BE-PFG record sheet as homework. This section consisted of reflective questions such as: “What was the outcome?”, “What have I learnt by completing this?” and “What is the strength of the target belief after an hour (0-100%)?” The forms were subsequently collected and entered into participants’ medical records by program staff.

Data source

The data for this study were 183 BE-PFG record sheets completed by 52 participants in the period from March 2012 to March 2015. Prior to being given to the study team, all identifying information was removed from the record sheets. A participant number was written on each record sheet to identify where numerous record sheets had been completed by the same individual over time. To ensure anonymity of the data, no record of participant numbers and original participant details was retained.

Data analysis

To investigate the two research questions, 1) “What is the typical content of maladaptive beliefs?”, and 2) “How useful are Behavioural Experiments in validating or disproving the maladaptive beliefs of individuals with EDs?”, data analysis was undertaken in a two-stage process. Firstly, target beliefs identified by participants to be tested during the Behavioural Experiments were analysed. Following this, a process was established to examine whether, after the PFGs, participants were able to reflect upon the original target belief(s) identified. The analysis process is described in more detail below.

Stage One: Analysis of target beliefs

Target beliefs identified by participants in the BE-PFG record sheets were analysed using a thematic analysis approach [22]. All analyses were completed manually from the BE-PFG record sheets.

Emergent thematic coding proceeded in five phases [22]. In the first phase, the entire data set was read through twice. Detailed notes of identified preliminary patterns and potential

codes were made. In the second phase, initial codes were manually generated from re-reading participants' responses to the question, "**Target Belief** - what is your belief about what you are attempting?" Codes were generated for as many potential themes as possible. In the next phase, codes were analysed and synthesized to form preliminary themes. The labels corresponding with the codes and themes were closely aligned with the words used by the participants. In the fourth phase, preliminary themes were further reviewed, refined and condensed to ascertain the validity of individuals themes in relation to the entire data set. Finally, in the fifth phase, the final overarching themes were named and analysed for meaning.

Participants' responses were subsequently grouped under each of the identified themes. Most participants identified multiple target beliefs, which were therefore grouped under multiple themes. To ensure rigour of the analysis, participant responses were coded independently by the first author, then checked by the second author for consistency. When a difference in coding existed, the research team discussed the differences and mutually agreed upon a solution. While the researchers did not believe they had reached saturation of all possible themes, the analysis was starting to show overlapping themes emerging from the data.

Stage Two: Behavioural Experiment Feedback Loop

In the second stage of data analysis, a systematic method for exploring whether the behavioural experiment process had facilitated participants' reflection on their identified target beliefs was established. This process of analysis drew on numerous questions included in the BE-PFG record sheet. These included two questions from the section of the record sheet completed before the PFG, namely: (i) Target Belief - What is your belief about what you are attempting?; and (ii) Prediction - What you predict will happen either in the situation of afterwards. Three questions from the section of the record sheet completed after the PFG were also used for this analysis. These questions were: (i) After completing the experiment, was your prediction confirmed? If not, what happened? and (ii) What have I learnt by completing this?

A potential feedback loop emerged through the process of analysing participant responses to these questions. The sequence of actions within the feedback loop began with the identification of a specific target belief(s). Once the belief(s) were identified, participants

would formulate predictions as to what they thought would occur during the PFG activity. These predictions were often negative in nature, and bespoke of events occurring in a manner consistent with the validation of the previously identified target belief(s). Participants then engaged in a PFG and recorded the outcomes. Analysis of each participant's experience was conducted, with special attention being given to whether the previously formulated prediction actually eventuated. The subsequent reflection of each participant on their experience and what prediction eventuated resulted in the identification of 'what was learnt' by completing the experiment. Participant reflections on 'what was learnt' served to either directly or indirectly validate or disprove the target belief (refer to **Figure 1** for an example of the behavioural experiment feedback loop).

As most participants identified multiple target beliefs within each BE-PFG record sheet, most record sheets contained multiple potential feedback loops. Each feedback loop was analysed to determine if it was 'complete' or 'broken.' A feedback loop was considered as being 'complete' if the participant 1) stated a clear target belief, 2) stated a clear prediction, 3) participated in the behavioural experiment, 3) stated the outcome of the experiment, 4) reflected on what was they learned, and 5) could directly or indirectly validate or disprove the target belief through what was learnt. Alternately, a feedback loop was considered as being 'broken' if the participant did not link their reflections and what they learnt to the previously stated target belief. The analysis of the feedback loop process was used by the researchers as a means to evaluate if the BE had facilitated reflection on maladaptive beliefs.

After classifying each individual feedback loop as 'complete' or 'broken' these were tabulated according to the type of target belief being tested and the type of PFG (i.e., Cooking PFG or Dining Out PFG) undertaken. The different types of PFGs were analysed separately to explore whether there were any potential differences in the types of target beliefs tested or in the outcomes in terms of feedback loops.

A research journal was maintained throughout both stages of the data analysis process to track emerging data patterns, note preliminary interpretations of the data, and to record rationales and justifications for the coding and feedback loop process. A reflective journal was also used to ensure that the researcher's personal views, opinions and biases were contained. The researchers shared and discussed the reflections during each stage of the data analysis process in order to maintain consistent condensing and interpretation of the data.

[Insert Figure 1 Here]

Results

Analysis of target beliefs findings

Ten key themes emerged from the analysis of target beliefs. These themes were: 1) Forbidden foods; 2) Portion sizes; 3) Beliefs about weight; 4) Negative Self-Beliefs; 5) Negative emotions; 6) Shopping and eating in public; 7) Decision making; 8) Compensatory behaviours; 9) Need for control; and 10) Cooking skills. These key themes are depicted in **Table 1**.

Theme 1: Forbidden Foods

Target beliefs that focussed on participants' preoccupation with *forbidden foods* emerged as being the most predominate within the data, being cited by 40 participants. Foods that fell into this category were often labelled as being unhealthy, unnecessary, fattening or lacking nutritional value. They were also identified as containing excessive amounts of sugars, fats and oils, as well as having too many calories. Forbidden foods were also labelled as 'trigger' foods that would lead result in the urge to engage in compensatory behaviours such as vomiting or restrictive eating. For those reasons, participants reported that forbidden foods should only be consumed on special occasions or in small quantities, if at all.

Theme 2: Portion sizes

Target beliefs regarding food *portion sizes* emerged as another major theme, cited by 22 participants, particularly during 'Dining Out' PFGs. Participants believed that portion sizes offered by restaurants were often too large and excessive. Participants reported that consuming such large quantities of food would either trigger the urge to engage in compensatory behaviours or result in uncomfortable feelings of fullness. Large portion sizes were also reported as being "unhealthy" or "fattening." Alternately, a small number of participants reported having concerns that restaurant portions would be too small and would subsequently trigger the urge to binge.

Theme 3: Beliefs about weight

Nineteen participants reported target beliefs that centred on *beliefs about weight*, namely weight gain. BEs during which participants were expected to consume foods with high levels of sugars, fats, oils and carbohydrates often resulted in participants reporting their expectation of inevitably putting on excessive amounts of undesired weight. Target beliefs

about weight gain were often coupled with target beliefs that focussed on forbidden foods and portion sizes.

Theme 4: Negative self-beliefs

Fourteen participants reported target beliefs focused on *negative self-beliefs*. These beliefs were made up primarily of negative self-judgements about participants' self-worth, self-control and body image.

Theme 5: Negative emotions

Twelve participants identified target beliefs regarding the expectation of experiencing *negative emotions* as a result of participating in the behavioural experiment. These included feelings of stress, anxiety, fear, discomfort, disgust, regret and shame. Target beliefs regarding the expected experience of negative emotions were often coupled with, or embedded in, statements about negative self-beliefs, forbidden foods, portion sizes and eating in public.

Theme 6: Shopping and eating in public

Target beliefs focussed on issues relating to *shopping and eating in public* emerged on the BE-PFG record sheets of 10 participants, particularly in the 'Dining Out' PFGs data set. Participants reported being fearful or having a strong dislike of eating in public. Fear of being negatively judged for their food choices by other people was cited as one of the reasons for participants' dislike for eating in public. These target beliefs were occasionally coupled with, or embedded in, beliefs regarding the expectation of experiencing negative emotions.

Theme 7: Decision-making

Ten participants, solely within the 'Dining Out' PFG data set, cited *decision-making* target beliefs. Participants reported expecting to have difficulty making menu choices at restaurants as a direct result being presented with, and subsequently being overwhelmed by, too many options. Consequently, participants believed that they would take long periods of time to make their decisions.

Theme 8: Compensatory behaviours

Nine participants cited target beliefs concerning the need to engage in *compensatory behaviours*. The most commonly stated behaviours included plans to restrict future food intake, consume ‘safe foods’ with lower caloric content later on during the day, or plans to purge after the experiment.

Theme 9: Need for control

Eight participants cited the *need for control*, or discomfort with the lack of having control, as target belief. Within the ‘Cooking’ group, participants reported their discomfort over not having control over the situation or environment (kitchen), and not having control over other participants making and handling their food. In the ‘Dining Out’ group, participants believed that they would experience high levels of distress if they did not have control over their eating disorder thoughts when making food choices, alongside being uncomfortable with not knowing what menu options will be available beforehand.

Theme 10: Cooking skills

Eight participants identified their lack of practical cooking skills and/or lack of knowledge about the cooking process as a target belief within the ‘Cooking’ PFGs data set. More specifically, participants most often cited their inability to follow recipe instructions precisely, and lack of knowledge of how to measure ingredients correctly as their primary target belief. As a result, participants reported that they would worry excessively that they would make mistakes and ruin the meal.

[Insert Table 1 Here]

Behavioural Experiment Feedback Loop Findings

The behavioural experiment feedback loop was used for the purposes of detecting any positive or negative changes in participants’ already existing maladaptive beliefs. The combined number of feedback loops associated with each target belief can be seen in **Table 2**.

[Insert Table 2 Here]

The total number and percentage of ‘complete’ and ‘broken’ feedback loops for the ‘Dining Out PFG’ can be seen in **Table 3**. Sixty-eight percent of the feedback loops within this data set were ‘broken’. This was a result of: 1) participants reflecting on various other perceived benefits and/or negative consequences of engaging in the behavioural experiment, or 2) participants providing vague or non-specific reflections, or 3) participants having

identified beliefs that could not be reflected upon shortly after engaging in an experiential activity or 4) participants not recording any reflections.

[Insert Table 3 Here]

The total number and percentage of ‘complete’ and ‘broken’ feedback loops for the ‘Cooking’ PFGs can be seen in **Table 4**. Sixty-nine percent of the feedback loops within this data set were ‘broken’. Broken feedback loops occurred for many of the same reasons as those previously mentioned for the ‘Dining Out’ PFG. However, unique to the ‘Cooking’ PFG data set, is the finding that some loops were broken as a result of participants experiencing what has been termed the ‘cooking class effect.’ This ‘cooking class effect’ was present in nine feedback loops and was present when participants reflected on their improved or newly acquired cooking skills or the product of the cooking group as opposed to reflecting on their target belief(s).

[Insert Table 4 Here]

Discussion

This study adds to the existing literature in two ways. Firstly, results highlight the range of maladaptive beliefs held by a group of individuals with EDs about food and eating. Secondly, the study has demonstrated that BEs have the potential to be a useful tool to assist individuals to reflect upon and challenge these maladaptive beliefs. However, the large proportion of behaviour experiments where the “feedback loop” was not completed suggests that this potential is not always realised.

Typical content of maladaptive beliefs

Participants often endorsed a wide range of key maladaptive beliefs. More specifically, the data suggested that the most recurrent content of maladaptive beliefs targeted for testing using BEs, focussed on forbidden foods, beliefs about weight and portion sizes. Concerns regarding the caloric content, nutritional value, macronutrient composition and quantity of food, alongside concerns about weight gain, were at the centre of these themes. Similarly, beliefs about negative emotions and negative self-beliefs were frequently cited. These findings are consistent with a number of studies which have identified negative self-beliefs, assumptions about weight, shape and eating as the frequent content of maladaptive beliefs [23][24][18]. However, previous research has tended to focus on identifying underlying assumptions and core dysfunctional beliefs in the context of social- and self-

desirability [18], with little research concentrating specifically on the content of beliefs in relation to food and the experience of eating. As maladaptive beliefs focused on food and eating have been described as causal factors in the manifestation of decreased levels of self-efficacy in eating and increased levels of eating disorder symptoms [25][26], findings from this study are particularly helpful. The identification and challenging of these beliefs is required to improve eating behaviour and self-efficacy in relation to nutritional intake and weight control [26], alongside improving motivation to engage in the self-care task of eating [27].

Broken Behavioural Experiment Feedback Loop

The adoption and use of unmodified traditional Behavioural Experiment record sheets with individuals with EDs in a group based therapy setting may not allow for the maximum treatment potential of BEs to be realized. More specifically, the data revealed that the majority of identified target beliefs were not validated or disproven. This was primarily caused by the lack of engagement in self-reflection following experiential activities. Almost 70% of the behavioural experiment feedback loops were deemed to be ‘broken’. Three potential causal factors of this occurrence were hypothesized: (i) the identification of, and attempt to test, more than one maladaptive belief within a single experiential activity, (ii) the failure to reflect upon the originally identified target belief(s), and (iii) the lack of suitability of traditional BE record sheet formats for use in group contexts and for individuals with EDs.

This interpretation of these data is supported by several observations made by the researchers. Firstly, despite having more than one identified maladaptive belief prior to engagement in an experiential activity, documented reflections on ‘what was learnt’ often addressed only one of the listed maladaptive beliefs. In some instances, this was due to the identification of, and attempt to test, beliefs that could neither be validated nor disproven shortly after engagement in an experiential activity. This was most apparent in relation to beliefs about gaining weight. This resulted in such beliefs not being reflected upon. In other instances, documented reflections did not address any of the identified belief(s) targeted for testing. But instead, were focused on alternative benefits and/or negative consequences of participating in experiential activities. By way of example, the manifestation of what the researchers have referred to as the ‘cooking class effect’ was the direct result of participants reflecting upon their improved or newly acquired cooking skills following engagement in the ‘Cooking’ PFGs. The ‘cooking class effect’ also served as unique evidence of the

distractibility of some participants from purpose of their engagement in the BEs. Lastly, a small number of BE-PFG record sheets had no documented reflections. All of these factors resulted in a large number of missed opportunities to directly reflect upon (i.e., validate or disprove) maladaptive beliefs; and ultimately clouded the evaluation of the potential usefulness of BEs in this context.

These findings are supported by previous research and publications regarding the importance of self-reflection as a key component of successful experiential learning [10][11][28][29]. The value and effectiveness of experiential learning in BEs is attributed as being partially derived from the field of adult education theory, in which the learning process proceeds in a series of Plan-Experience-Observe-Reflect cycles [11][29]. In the context of BEs, the learning cycle has been conceptualized as follows: collaborative planning in relation to which belief(s) will be tested, and how (plan); the patient then engages in an experiential activity (experience); the patient documents what eventuated (observe); then lastly, the patient reflects on what they learned in regards to their identified belief(s) [11]. Although all aspects of the cycle important, the process of self-reflection is highlighted as being the central determinant factor of influencing cognitive or behavioural change, whilst also promoting intrinsic learning in BEs [10][11][28].

The maladaptive beliefs identified by participants for testing often reflected upon one or more themes. By way of illustration, our findings showed that beliefs about weight gain were often coupled with beliefs that focussed on forbidden foods and portion sizes. Similarly, beliefs regarding negative emotions were often coupled with, or embedded in, beliefs about eating in public, forbidden foods, portion sizes and negative self-beliefs. This may serve as testament to the apparent complexity and multifaceted nature of maladaptive beliefs associated with food and the experience of eating. Furthermore, the multiplicity of these maladaptive beliefs, coupled with the traditional format of behavioural experiment record sheets, may act as a confounding factor to the process of self-reflection. The required scaffolding to support reflection is not easily achieved within the context of group therapy due to: 1) lack of time for one-on-one interactions between therapists and patients to prompt reflection, and 2) the lack of structures within the traditional BE record sheets to more actively prompt the process of reflection. Previous research have shown that, although group treatments are efficacious, individual treatments may be more successful in promoting and improving personal insight [30][31]. However, in the context of eating disorder treatment,

group interventions can be more cost-effective and provide an opportunity for mutual support which has been highlighted as especially helpful [32][33]. This presents a challenging situation for further development in this area of treatment.

Complete Behavioural Experiment Feedback Loops

Similar target beliefs were often identified by individuals over time, although these were not always recognised as the same by participants. This may be a result of participants regarding previously challenged maladaptive beliefs as being ‘new’ when presented in a different context. To illustrate, a participant may report believing that carbs in pizza are bad, but after engaging in an experiential activity, reflects upon and disproves that belief. However, in the following BE the same participant may report believing that carbs in cake are bad. This inability to realize that the belief that ‘carbs are bad’ has already been disproven, may speak of the need to provide participants with a structure in which to ‘cluster’ their beliefs. This may promote the realization of the transferability of newly established cognitions or beliefs. Cooper et al. [27], have recommended the use of diagnostic-specific models as potential frameworks from which to organize beliefs. A framework using the transdiagnostic model [34] allows beliefs to be organised into key cognitions associated with each of the five categories identified within this model: 1) Overevaluation of eating, weight, shape and their control, 2) Mood intolerance, 3) Core low self-esteem, 4) Perfectionism, and 5) Interpersonal problems.

Relevance for treatment

The present findings suggest that the adaptation of traditional behavioural experiment record sheets, in addition to extensive focus on promoting self-reflection may allow for better analysis of the treatment potential of BEs on individuals with EDs. The lack of extensive one-on-one collaboration between patients and therapists within a group-based therapy setting necessitates the revision of the BE-PFG record sheet, such that it inherently encourages self-reflection. This could be achieved by revising the final section of the record sheet and inserting questions that prompt patients to either re-state or re-read their identified target belief(s) after an experiential activity. This would provide additional scaffolding that may support more explicit reflection upon all identified target beliefs. Alternately, it may be helpful for therapists to encourage patients to review the completed BE-PFG forms at the beginning of the following therapy session. Emphasis should be placed on ensuring that identified beliefs were reflected upon and subsequently validated or disproven. This process

of reflection and consolidation of past experiences is an essential component to the treatment effectiveness of BEs [10][28].

In order to promote the transferability of newly acquired cognitions or beliefs, therapists may want to identify frameworks from which to organize maladaptive beliefs tested in BEs [27]. These frameworks would enable the ‘clustering’ of beliefs identified by patients to support information transferability, whilst also enabling and supporting repetition that is required to reinforce these new cognitions. The grading of experiential activities by increasing the level difficulty of BEs should also be considered in order to support growth over time [10][27][28]. This may be achieved by developing detailed hierarchies of feared foods and situations from which patients may start with content low on the hierarchy and work their way up [35][36]. This will also work to ensure the maintenance of the ‘Just Right’ challenge, in which ‘the challenge of an activity is slightly above what the patient is currently able to do’[37]. In the context of BEs, chosen maladaptive beliefs and experiential activities may be graded such that they are progressively challenging, but always achievable so patients can continue to learn from their experiences.

Scope and Limitations

Although the current study has resulted in a number of important implications for practice, the findings may be limited due to a number of factors. Firstly, this study was conducted with data from female participants engaged with a specialist eating disorders Day Program in a single geographical location. Future research will be needed to determine if the findings are representative of the typical content of maladaptive beliefs using a larger, more diverse population sample. Beyond this point, a larger sample may enable the exploration of whether the factors that led to the low level of “completed” feedback loops observed in this study is present in other similar programs. Furthermore, the use of the traditional behavioural experiment record sheet did not allow for the determination of changes in maladaptive beliefs. Specifically, the measure allowed for the identification of numerous target beliefs within a single experiential activity, however the measure was not constructed such that it elicited the corresponding amount of self-reflection required to consistently validate or disprove beliefs and to track these changes over time. Further research will be necessary to determine changes in beliefs through the use of behavioural experiment record sheets that are better adapted for use in the treatment of EDs in a group-based therapy setting. Lastly, the recurrent incognizant testing of similar-identical beliefs diminished the value of repetitious testing of beliefs. As

such, the transferability and application of new knowledge did not eventuate, and subsequently hindering the ability of researchers to determine the usefulness of BEs.

Conclusions

The endorsement of a wide range of maladaptive beliefs regarding forbidden foods, portion sizes, weight concerns, negative-self beliefs, negative emotions, decision-making abilities, cooking skills, eating in public, the need for control and compensatory behaviours are characteristic of individuals with disordered eating. The identification of multiple beliefs, in conjunction with the existence of more than one theme within a single belief may necessitate the need for refinement of the Behavioural Experiment record sheets for use within the context of group-based therapy. This study demonstrated that current structure of the BE-PFG record sheet was not always successful in eliciting self-reflection which resulted in missed opportunities for patients, therapists and researchers to realize the full treatment potential of BEs. The BE-PFG record sheet requires ongoing development and refinement in order to better achieve the aim of influencing changes in the maladaptive beliefs of individuals with EDs. If improved, the missed opportunities of validating or disproving maladaptive beliefs might be addressed by ensuring engagement in self-reflection following experiential activities.

Declaration of interest

The authors declare that they have no competing interests.

Author contributions

All authors were involved in the conception and design of the research. MM developed codes for, analysed and interpreted the data, and wrote the manuscript under the supervision and with the assistance of the other authors. JNS interpreted the data and co-authored the manuscript. All authors read and approved the final manuscript.

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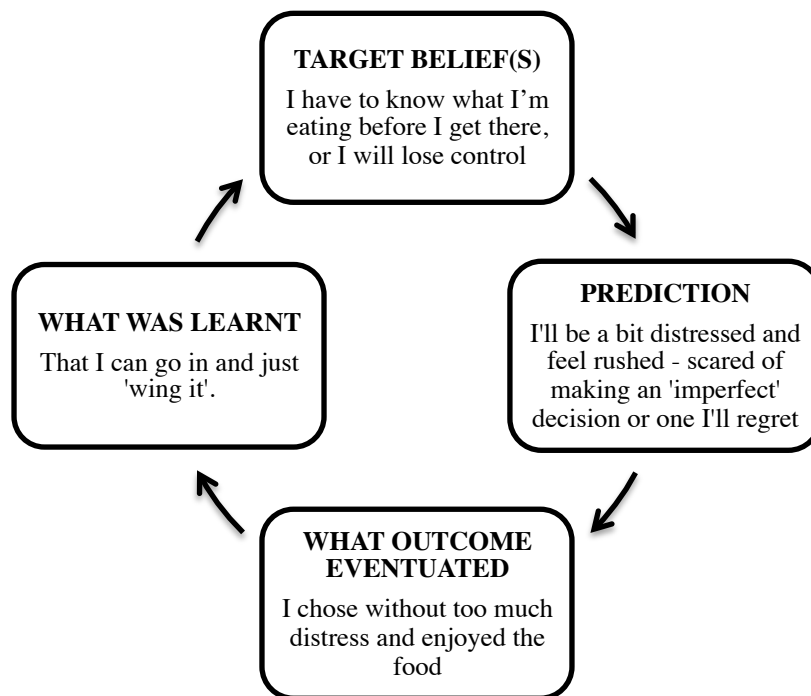
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FIGURES

Figure 1. ‘Complete’ behavioural experiment feedback loop

Figure 1. 'Complete' Behavioural Experiment Feedback Loop



TABLES

- Table 1. Themes and specific examples of cited target beliefs
- Table 2. Behavioural experiment feedback loop frequencies
- Table 3. ‘Dining Out’ target belief and feedback loop frequencies
- Table 4. ‘Cooking Group’ target belief and feedback loop frequencies

Table 1. Themes and specific examples of cited target beliefs

Themes	Participant Quotes Participant number is shown in parentheses	Number of Participants
Forbidden Foods	“Muffins are unhealthy, dangerous foods.” (10) “Ice-cream should only be eaten on special occasions or not at all.” (22) “Eating fast food is a no-no.” (34)	40
Portion Size	“The portion size will be way too big.” (7) “A bit scared about the portion size. It’s always much bigger at restaurants.” (31) “Portion sizes at restaurants are too big.” (50)	22
Beliefs about weight	“Thai food is full of carbs, fat and oils and will make me fat.” (19) “I’ve eaten so much and I haven’t eaten ‘bad’ foods in so long. It will make my weight increase drastically.” (31) “I will get fat.” (37)	19
Negative self-beliefs	“I’m too fat to eat cake.” (19) “I should never eat this type of food because I am overweight.” (26) “I will explode. My stomach will burst.” (38)	14
Negative emotions	“Will feel very uncomfortable being around so much fun food and only being allowed 1 piece.” (16) “I will get anxious and overwhelmed by the choices.” (30) “I can eat but I will be anxious.” (36)	12
Shopping and eating in public	“Eating in a food court raises some anxiety.” (3) “I will feel self conscious eating in public.” (6) “Everyone will notice me eating and judge me.” (52)	10
Decision making	“I won’t know what to choose.” (13) “Healthy self-arguing with ED when choosing whether I’m choosing right thing.” (19) “I won’t be able to make a decision.” (34)	10
Compensatory behaviours	“Non-complex carbs are not healthy and to make up for enjoying those means I cannot have other foods I enjoy later in the day.” (14) “Can’t have burger and chips in the same meal without affecting another meal. Should strict later.” (37) “I may want to cut carbs later on for dinner.” (45)	9
Need for control	“Other people shouldn’t be touching my food -	8

	<p>they'll make it wrong." (5)</p> <p>"Will be stressful, feel anxious about not being in control of the situation." (28)</p> <p>"I won't like it that others are preparing food for me." (40)</p>	
Cooking skills	<p>"That I'm a BAD cook! Believe it will help me learn how to cook properly. Learn portioning and helping everyday cooking." (15)</p> <p>"I'm not good enough at cooking yet, I lack knowledge about cooking and different foods and will make mistakes or ruin it." (20)</p> <p>"I suck at cooking so I'm going to mess it up." (29)</p>	8

Table 2. Behavioural Experiment Feedback Loop Frequencies

Target belief	Total Number of Feedback Loops N = 279
1) Forbidden foods	122 (43.7%)
2) Beliefs about weight	36 (12.9%)
3) Portion Sizes	28 (10.0%)
4) Negative self-beliefs	20 (7.2%)
5) Decision making	17 (6.1%)
6) Negative emotions	17 (6.1%)
7) Shopping and eating in public	12 (4.3%)
8) Compensatory behaviours	10 (3.6%)
9) Need for control	9 (3.2%)
10) Cooking	8 (2.9%)

Table 3. ‘Dining Out’ target beliefs & feedback loop frequencies

Target belief	Frequencies	Feedback Loops	
		Complete	Broken
1) Forbidden foods	96	31 (32%)	65 (68%)
2) Beliefs about weight	29	0 (0%)	29 (100%)
3) Portion Sizes	24	7 (29%)	17 (71%)
4) Negative self-beliefs	16	7 (44%)	9 (56%)
5) Decision making	17	13 (76%)	4 (24%)
6) Negative emotions	13	6 (46%)	7 (54%)
7) Shopping and eating in public	11	6 (55%)	5 (45%)
8) Compensatory behaviours	9	0 (0%)	9 (100%)
9) Need for control	5	1 (20%)	4 (80%)
10) Cooking	0	-	-
	N = 220	N = 71 (32%)	N = 149 (68%)

Table 4. ‘Cooking Group’ target beliefs and feedback loop frequencies

Target belief	Frequencies	Feedback Loops	
		Complete	Broken
1) Forbidden foods	26	6 (23%)	20 (77%)
2) Beliefs about weight	7	0 (0%)	7 (100%)
3) Portion Sizes	4	1 (25%)	3 (75%)
4) Negative self-beliefs	4	1 (25%)	3 (75%)
5) Decision making	0	-	-
6) Negative emotions	4	1 (25%)	3 (75%)
7) Eating in public	1	0 (0%)	1 (100%)
8) Compensatory behaviours	1	0 (0%)	1 (100%)
9) Need for control	4	1 (25%)	3 (75%)
10) Cooking skills	8	8 (100%)	0 (0%)
	N = 59	N = 18 (31%)	N = 41 (69%)

SECTION 3: APPENDICIES

Appendix A: Behavioural Experiment – Practical Food Group record sheet

Appendix B: Journal of Eating Disorders Author Guidelines

Appendix C: Participant Information Sheet and Consent Form

Appendix A: Behavioural Experiment – Practical Food Group record sheet

NAME:

DATE:

Behavioural Experiments – PRACTICAL FOOD GROUP

Behavioural experiments are the real-life, lived experiences you will have in treatment that will challenge your ED beliefs. Planning beforehand and debriefing afterwards is equally important to what you are attempting to do. BE's have their three purposes: to find out more about the eating disorder; to test your thoughts and beliefs; and, to construct more adaptive and realistic objective is not to modify thinking per se, but rather, through cognitive change from real-life experience, to shift automatic emotional responses and facilitate problem solving.



'I understand them as being ways of checking out things, finding out if certain beliefs I had were true by going into situations...Deciding beforehand what I was worried might happen and then trying to see if it did happen.'

1. What I will be attempting – the where, when, how, length of time etc., so we can tell if you have completed what you have set out to do. Be specific

2. Target Belief – what is your belief about what you are attempting?

Strength of target belief (0-100%):

3. Prediction – what you predict will happen either in the situation or afterwards.

Strength of prediction (0-100%):

4. Alternative prediction – what might be a different and realistic outcome?

Strength of alternate prediction (0-100%):

5. What could be the best outcome?

6. What skills are you going to practice?

7. My safety behaviours (things that I do to compensate for, or decrease engagement in what I'm attempting...subtle or obvious) are:

- 1)
- 2)
- 3)
- 4)
- 5)

8. What is the biggest hurdle to overcome in attempting this BE?

9. How confident do you feel? How **important** is this BE? Confidence ___% Importance ___%
0% = Nil -----50-----100% Max conf/importance

Questions to ask yourself as you are attempting the BE:

What did I just notice? What is running through my mind just now?

Remember that the emotions will gradually decrease over time, we're just unsure of how long it will take. What do you notice around you? Can you do 5,5,5 while you are surfing the emotions?

Brook Adam, Clinical Psychologist 2012. Modified by Jessica Wheatley, Occupational Therapist, for practical food groups 2012
H:\Common\Day program\RPAH Dayprogram CLIN PSYCH\Program\3. MODULE CBT\Behavioural Experiments

Behavioural Experiment – Practical Food Group record sheet continued

NAME:

DATE:

Are you checking changes in the degree of belief in target cognitions, predictions, and alternative perspectives as the experiment progresses? Are you carefully monitoring changes in your emotional state?

Are you alert for your thoughts and safety behaviours during the experiment?

Have you worked out how to avoid discouragement if this doesn't go as well as you hope?

Reflection Question: Are you prepared for **full engagement** in the experiment, with **mindful awareness** of what is going on? Will I attempt to be fully immersed in the experiment, rather than 'going through the motions' or using subtle avoidance?

After completing the behavioural experiment...

1. What was the outcome i.e. what did you do **specifically**?
2. What is the strength of the target belief after an hour (0-100%)
3. How strong is your anxiety?
 - a. 30minutes before:
 - b. During the experiment:
 - c. After one hour:
 - d. After three hours:
 - e. 24 hours later:
4. After completing the experiment, was your prediction confirmed?
5. Did the alternative prediction eventuate?
6. Did you engage in any safety behaviours? If yes, what?
7. What was the biggest challenge in doing this?
8. What have I learnt by completing this?
9. Objectively, was this a success? Why or why not?
10. What is the next step?
11. When will you repeat this experiment in the next 5 days and with who?

Instructions for authors

Research articles

Presubmission enquiries | Submission process | Preparing main manuscript text | Preparing illustrations and figures | Preparing tables | Preparing additional files | Style and language

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- Title page
- Abstract
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- Background
- Methods
- Results and discussion
- Conclusions
- List of abbreviations used (if any)
- Competing interests
- Authors' contributions
- Authors' information
- Acknowledgements
- Endnotes
- References
- Illustrations and figures (if any)
- Tables and captions
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The **Accession Numbers** of any nucleic acid sequences, protein sequences or atomic coordinates cited in the manuscript should be provided, in square brackets and include the corresponding database name; for example, [EMBL:AB026295, EMBL:AC137000,

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The databases for which we can provide direct links are: EMBL Nucleotide Sequence Database (EMBL), DNA Data Bank of Japan (DDBJ), GenBank at the NCBI (GenBank), Protein Data Bank (PDB), Protein Information Resource (PIR) and the Swiss-Prot Protein Database (Swiss-Prot).

For reporting standards please see the information in the about section.

Title page

The title page should:

- provide the title of the article
- list the full names, institutional addresses and email addresses for all authors
- indicate the corresponding author

Please note:

- abbreviations within the title should be avoided
- if a collaboration group should be listed as an author, please list the Group name as an author. If you would like the names of the individual members of the Group to be searchable through their individual PubMed records, please include this information in the “acknowledgements” section in accordance with the instructions below. Please note that the individual names may not be included in the PubMed record at the time a published article is initially included in PubMed as it takes PubMed additional time to code this information.

Abstract

The Abstract of the manuscript should not exceed 350 words and must be structured into separate sections: **Background**, the context and purpose of the study; **Methods**, the methodology and type of analysis; **Results**, the main findings; **Conclusions**, brief summary and potential implications. Please minimize the use of abbreviations and do not cite references in the abstract.

Keywords

Three to ten keywords representing the main content of the article.

Background

The Background section should be written in a way that is accessible to researchers without specialist knowledge in that area and must clearly state - and, if helpful, illustrate - the background to the research and its aims. The section should end with a brief statement of what is being reported in the article.

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The methods section should include the design of the study, the type of materials involved, a clear description of all comparisons, and the type of analysis used, to enable replication.

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The Results and discussion may be combined into a single section or presented separately. The Results and discussion sections may also be broken into subsections with short, informative headings.

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This should state clearly the main conclusions of the research and give a clear explanation of their importance and relevance. Summary illustrations may be included.

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Article within a journal by DOI

Slifka MK, Whitton JL. Clinical implications of dysregulated cytokine production. *Dig J Mol Med*. 2000; doi:10.1007/s801090000086.

Article within a journal supplement

Frumin AM, Nussbaum J, Esposito M. Functional asplenia: demonstration of splenic activity by bone marrow scan. *Blood* 1979;59 Suppl 1:26-32.

Book chapter, or an article within a book

Wyllie AH, Kerr JFR, Currie AR. Cell death: the significance of apoptosis. In: Bourne GH, Danielli JF, Jeon KW, editors. *International review of cytology*. London: Academic; 1980. p. 251-306.

OnlineFirst chapter in a series (without a volume designation but with a DOI)

Saito Y, Hyuga H. Rate equation approaches to amplification of enantiomeric excess and chiral symmetry breaking. *Top Curr Chem*. 2007. doi:10.1007/128_2006_108.

Complete book, authored

Blenkinsopp A, Paxton P. *Symptoms in the pharmacy: a guide to the management of common illness*. 3rd ed. Oxford: Blackwell Science; 1998.

Online document

Doe J. Title of subordinate document. In: *The dictionary of substances and their effects*. Royal Society of Chemistry. 1999. <http://www.rsc.org/dose/title of subordinate document>. Accessed 15 Jan 1999.

Online database

Healthwise Knowledgebase. *US Pharmacopeia*, Rockville. 1998. <http://www.healthwise.org>. Accessed 21 Sept 1998.

Supplementary material/private homepage

Doe J. Title of supplementary material. 2000. <http://www.privatehomepage.com>. Accessed 22 Feb 2000.

University site

Doe, J: Title of preprint. <http://www.uni-heidelberg.de/mydata.html> (1999). Accessed 25 Dec 1999.

FTP site

Doe, J: Trivial HTTP, RFC2169. <ftp://ftp.isi.edu/in-notes/rfc2169.txt> (1999). Accessed 12 Nov 1999.

Organization site

ISSN International Centre: The ISSN register. <http://www.issn.org> (2006). Accessed 20 Feb 2007.

Dataset with persistent identifier

Zheng L-Y, Guo X-S, He B, Sun L-J, Peng Y, Dong S-S, et al. Genome data from sweet and grain sorghum (*Sorghum bicolor*). GigaScience Database. 2011. <http://dx.doi.org/10.5524/100012>.

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- Description of data

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Additional file formats

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- Movies
 - MP4 (MPEG 4)
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- Tabular data
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As with figure files, files should be given the standard file extensions.

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5. Compress the folder into a ZIP, check the file size is under 20 MB, ensure that index.html is in the root of the ZIP, and that the file has .zip extension, then submit as an additional file with your article.

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Abbreviations

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- Please use double line spacing.
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- Use hard returns only to end headings and paragraphs, not to rearrange lines.
- Capitalize only the first word, and proper nouns, in the title.
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- Use the *Journal of Eating Disorders* reference format.
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Units

SI units should be used throughout (liter and molar are permitted, however).

Appendix C: Participant Information Sheet and Consent Form

ADDRESS FOR ALL CORRESPONDENCE
Royal Prince Alfred Hospital Day Program
Derwent House, 1-3 Derwent Street
Glebe NSW 2037

TELEPHONE 61 2 8587 0200
FACSIMILE 61 2 8587 0208
EMAIL mhedu@sswahs.nsw.gov.au



Evaluation of an Eating Disorder Day Program

INFORMATION FOR PARTICIPANTS

Introduction

You are invited to take part in an evaluation of the Royal Prince Alfred Hospital (RPAH) Eating Disorders Day Program. The primary aim of this research is to evaluate the effectiveness of treatment provided by this service. There are only a few public tertiary day patient treatment programs for eating disorders in NSW. The data collected from this research will be used both to evaluate the RPAH Day Program directly, and also to inform the development of further eating disorder service provision in NSW.

A further aim of this research is to identify any patient characteristics that are associated with better outcomes in treatment. It is hoped that this will enhance our general understanding of the effectiveness of specialist eating disorder treatment, as well as contributing to service improvements and best practice recommendations.

Key investigators in this study are:

- Professor Janice Russell (Medical Director of the Program)
- Dr Susan Hart (Coordinator of the Program)
- Sarah Horsfield (Clinical Research Psychologist with the Program)
- Jessica Aradas (Research Assistant with the Program)
- Dr Sarah Maguire (Eating Disorder Service Development Coordinator for NSW)

Study Procedures

If you agree to participate in this research, you will be asked to sign the *Participant Consent Form*. You will then undergo the routine assessments that form part of standard care, including a clinical interview and completion of surveys at admission, during treatment and at discharge. Being part of the study means that these assessments will be used for your clinical care and for the study.

Your treatment file will be reviewed for information such as weight, height, medication use and any medical problems associated with your eating disorder.

Finally, after you are discharged we would like to contact you again to complete some follow-up surveys to assess the long-term effects of your treatment. The follow-ups would take place for up to five years after you discharge from your final admission at Derwent House. We will contact you at 6, 12, 24, 36, 48 and 60 months after your discharge and ask

you to complete the surveys online. They would take approximately 45 to 60 minutes to complete on each occasion.

Benefits

Whilst we intend that this research study furthers our knowledge and may improve treatment of eating disorders in the future, it may not be of direct benefit to you.

Costs

Participation in this study will not cost you anything, nor will you be paid.

Voluntary Participation

The interviews and surveys used in this research are part of the standard clinical assessment in this service. However, you do not have to consent to the use of your information for research and service evaluation. If you do consent, you can withdraw this at any time without having to give a reason. Whatever your decision, please be assured that whether or not you choose to participate, it will not affect your treatment or your relationship with the staff who are caring for you.

Confidentiality

All data collected from you in relation to this study will be stored securely. However, since it may be used to inform your treatment in this service, the clinicians working with you in the program may have access to relevant clinical information. No-one other than the clinicians and the unit researcher will have access to identifiable data. Data used for research purposes will be coded. The research results may be presented at a conference or in a scientific publication, but no information that could identify you will be presented.

Further Information

When you have read this information, *your interviewer* will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact the Coordinator of Day Patient Program, Susan Hart on 02 8587 0200 or mhedu@sswahs.nsw.gov.au

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 and quote protocol number X10-0214.

This information sheet is for you to keep.

Thank you for taking time to consider this study.

THE PARTICIPANT CONSENT FORM (PARTICIPANTS COPY)

I, [Name]

Of[Address]

have read and understood the *Information for Participants* on the above named research study and have discussed the study with the researcher

[insert name of researcher]:

I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

I understand that my participation in this study will allow the researchers to have access to my medical record, and I agree to this.

I freely choose to participate in this study and understand that I can withdraw at any time.

I also understand that the data collected for research will be strictly confidential.

I hereby agree to participate in this research study.

NAME:

SIGNATURE:

DATE:

NAME OF WITNESS:

SIGNATURE OF WITNESS:

THE PARTICIPANT CONSENT FORM (RESEARCHER'S COPY)

I, [Name]

Of[Address]

have read and understood the *Information for Participants* on the above named research study and have discussed the study with the researcher

[insert name of researcher]:

I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

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I hereby agree to participate in this research study.

NAME:

SIGNATURE:

DATE:

NAME OF WITNESS:

SIGNATURE OF WITNESS:

(PARTICIPANT'S COPY)