VOLUME ONE

RESEARCH COMPONENT

THE IMPACT OF MINDFULNESS-BASED APPROACHES ON EATING BEHAVIOUR IN CHILDREN AND ADULTS

by

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A THESIS SUBMITTED TO THE UNIVERSITY OF BIRMINGHAM FOR THE DEGREE OF DOCTOR OF CLINICAL PSYCHOLOGY

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May 2018

Overview

This thesis, submitted in partial fulfilment of the requirements of the degree of Doctorate in Clinical Psychology, consists of two volumes. Volume One is a research component, consisting of a systematic review and meta-analysis, an empirical study and a public dissemination document. Volume Two is a clinical component, consisting of five clinical practice reports.

The first paper in Volume One is a meta-analysis of research on the effectiveness of Dialectical Behaviour Therapy to reduce binge eating episode frequency in individuals with sub- and full-threshold Bulimia Nervosa and Binge Eating Disorder. The second paper is an empirical research study of the effectiveness of mindfulness for improving novel food acceptance in 10-12-year-olds. The third paper is a summary report for the dissemination of findings by the public and other stakeholders.

The first report in Volume Two is a case formulation, of a 36-year-old male with a mild learning disability presenting with angry outbursts, from cognitive behavioural and systemic perspectives. The second report is an audit of adherence to a NICE Quality Standard on Anxiety Disorders in a community service for adults with learning disabilities. Report three is a case study of a 28-year-old female with Borderline Personality Disorder, referred to a Complex Care Service for low mood, anger and shame. The fourth report is a single case experimental design evaluating the effectiveness of cognitive-behavioural work with an 8-year-old female with Obsessive Compulsive Disorder. The final report summarises the (neuropsychological) assessment of a 60-year-old female with Alzheimer's Disease.

All identifying information has been omitted to maintain the confidentiality of individuals and services described throughout this thesis.

For nanny, who taught me to *never* give up

Acknowledgements

Firstly, I would like to thank my supervisors Professor Jackie Blissett and Professor Alex Copello for their support, guidance and containment over the last three years and beyond! I couldn't have asked for a better team and am incredibly grateful that you both took me on and made this process enjoyable. You have both been an inspiration to me and I will hold on to the enthusiasm and passion you shared with me as I continue on my journey.

I would also like to thank Dr Chris Jones for sharing his amazing, vast and terrifying knowledge of statistics with me. Your input at all stages of this project has been invaluable.

I would like to thank the schools, children and families for taking part in this research and for sharing my enthusiasm for this project.

A big thank you also goes out to my family who has supported me through yet another doctorate by supplying plenty of reassurance, words of wisdom and most importantly, biscuits.

Finally, I would like to thank David for making sure that the last three years never got boring, for believing in me (even when I did not) and for supporting me even when it was difficult.

I promise this will be my last doctorate... probably.

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VOLUME ONE
Research Component

LITERATURE REVIEW

The effectiveness of Dialectical Behaviour Therapy for binge eating behaviour in Bulimia Nervosa and Binge Eating Disorder:

A Meta-Analysis

Abstract

Background: Bulimia Nervosa (BN) and Binge Eating Disorder (BED) are associated with poor emotion regulation. Cognitive behavioural interventions are not always effective in supporting individuals to overcome these difficulties. Dialectical Behaviour Therapy (DBT) aims to support emotion regulation skills and may be a promising alternative. The present meta-analysis evaluated the effectiveness of DBT in reducing binge eating episode frequency in individuals with sub- and full-threshold BN and BED.

Method: A systematic literature search of PsychINFO, Medline and EMBASE databases generated 14 eligible articles, which were rated on quality.

Results: The results of the meta-analysis revealed very large effects of DBT on binge eating episode frequency; binge eating episode frequency was significantly reduced for individuals engaging in DBT. Sensitivity analyses indicated that family involvement and the composition/qualification of the therapist team had a significant impact on the meta-analytic effect.

Discussion: The results suggest that DBT is linked with a reduction in binge eating episode frequency. Nevertheless, factors such as the integration of family members into treatment and treatment delivery need to be explored further. Fidelity of treatment delivery was inconsistently measured and rarely reported. More studies with robust designs, larger samples and longer follow-up periods are needed to corroborate these promising findings.

Introduction

A number of psychological interventions have been developed for the treatment of eating disorders such as Bulimia Nervosa (BN) and Binge Eating Disorder (BED). Cognitive behavioural approaches are recommended by the National Institute for Health and Clinical Excellence (NICE) but these are not always effective in treating BN and BED (NICE, 2017). Consequently, a growing body of research is exploring the effectiveness of third wave cognitive behavioural approaches such as Dialectical Behaviour Therapy (DBT) to support individuals affected by these eating disorders (Gale, Gilbert, Read, & Goss, 2014). DBT focuses on learning more adaptive emotion regulation skills, targeting behaviours that arise in the context of emotional dysregulation (Linehan, 1993). This therapeutic approach in particular may be relevant to the treatment of BN and BED, as the problematic behaviours associated with these eating disorders are thought to be driven by emotion regulation difficulties (McCabe, LaVia, & Marcus, 2004). The following sections will firstly explore the diagnostic criteria, prevalence and course of BN and BED. Secondly, evidence-based interventions for BN and BED will be outlined. Finally, DBT will be introduced and evidence for its effectiveness in this population will be presented.

Bulimia Nervosa and Binge Eating Disorder

BN and BED are both formally recognised in the Diagnostic and Statistical Manual of Mental Disorders (DSM, American Psychiatric Association [APA], 2013). The most recent revision of the clinical criteria for BN and BED reported in the DSM-V are presented in Appendix A. Around 1-2% of women in Europe suffer from BN and 1-4% from BED (Keski-Rahkonen & Mustelin, 2016). Between 0.3 and 0.7% of

men in Europe suffer from an eating disorder; the ratio of males to females with diagnoses of BN and BED is 1:4 (Keski-Rahkonen & Mustelin, 2016).

BN was first clinically described by British Psychiatrist Gerard Russell in 1979 and included in the DSM-III (Castillo & Weiselberg, 2017; Fairburn & Beglin, 1990). Individuals suffering from BN are extremely concerned about and preoccupied with their body shape and weight, but tend to have a normal body weight (Brownell & Walsh, 2017). BN is characterised by recurrent episodes of binge eating (at least once per week over three months) followed by purging behaviours that include self-induced vomiting, the use of laxatives or diuretics, excessive exercise, adherence to strict dieting rules and intake control (APA, 2013; Fairburn & Beglin, 1990). A binge eating episode is defined as the ingestion of an unusually large amount of calories over a discrete period of time (<2h) in which there is a perceived loss of control over intake (Castillo & Weiselberg, 2017). The engagement in compensatory behaviours is linked with a significant risk for morbidity and mortality (Westmoreland, Krantz, & Mehler, 2016). Additionally, there is a high degree of comorbidity between BN and mental health disorders such as depression, anxiety disorders and substance use disorders, which if untreated, increase the risk of morbidity and mortality further (O'Brien & Vincent, 2003). A significant co-morbidity between BN and Borderline Personality Disorder has also been noted (Bankoff, Karpel, Forbes, & Pantalone, 2012).

BED was only formally recognised in DSM-V. It was previously included under the category of Eating Disorders Not Otherwise Specified (Grilo, Ivezaj, & White, 2015). BED is characterised by recurrent episodes of bingeing (at least once per week over three months) in the absence of the compensatory behaviours associated

with BN. Individuals with BED typically experience distress about binge eating episodes, which are marked by a loss of control (de Zwaan, 2001). Individuals with BED tend to be overweight or obese, although some maintain a normal weight (Brownell & Walsh, 2017).

Research suggests that emotional dysregulation underlies problematic behaviours exhibited in BN and BED, with negative emotional states preceding the occurrence of binge eating episodes (Bankoff et al., 2012). Individuals may try to regulate distressing emotional states through the use of binge eating, which leads to a reduction in these emotional states in the short term, reinforcing future reliance on this behaviour. Nevertheless, binge eating and the use of compensatory behaviours also foster negative emotional states such as guilt and shame in the long-term, thereby leading to a vicious cycle of negative emotions and dysfunctional eating patterns (Stewart, Voulgari, Eisler, Hunt, & Simic, 2015).

BN and BED differ in course and outcome, as BN is associated with more enduring difficulties with eating behaviour and a greater risk of relapse than BED (Fairburn, Cooper, Doll, Norman, & O'Connor, 2000). Both are, however, associated with low treatment seeking, which may be due to the associated shame, guilt and stigma (Hepworth & Paxton, 2007).

Evidence-Based Interventions for BN and BED

Interventions for BN and BED include psychotherapeutic approaches that can be combined with psychopharmacological tools (Mitchell, Agras, & Wonderlich, 2007). Intervention targets include the breakdown of the binge-purge cycle, the reintroduction of non-problematic eating patterns, addressing the physical impact of the disorders (e.g. enamel erosion and abnormalities in fluids and electrolytes in BN),

exploring psychological factors underlying the development and maintenance of the difficulties (e.g. low self-esteem, body image dissatisfaction), working with co-morbidities such as anxiety and depression, and preventing relapse (Mitchell et al., 2007).

The interventions that have received most attention include different formats of cognitive behavioural therapy and psychodynamic interpersonal therapy (Cochrane review: Hay, Bacaltchuk, Stefano, & Kashyap, 2009; Mitchell et al., 2007). NICE (2017) recommends that interventions are delivered as part of a stepped-care framework, hence BN-focused cognitive behavioural guided self-help is suggested for adults suffering from BN, which can be stepped up to individual eating disorder-focused CBT. For children suffering from BN, BN-focused Family Therapy, or if this is ineffective, individual eating disorder-focused CBT, is recommended. NICE (2017) also recommends BED-focused cognitive behavioural guided self-help for children and adults with BED. This can be stepped up to group or individual eating disorder-focused CBT if necessary. Pharmacological interventions may be used in the context of addressing co-morbid mental health difficulties. See Appendix B for an overview of NICE-recommended treatments for adults and children.

What is Dialectical Behaviour Therapy?

Research has indicated that as many as 50% of treatment-seeking individuals continue to engage in binge eating behaviour after participating in recommended interventions (Telch, Agras, & Linehan, 2001). This has sparked exploration of alternative interventions such as DBT. DBT is a third wave cognitive behavioural approach developed by Marsha Linehan. It was originally developed as a treatment for individuals engaging in suicidal and self-harm behaviours meeting diagnostic

criteria for Borderline Personality Disorder (Linehan, 1993). Standard DBT lasts for a year and involves weekly sessions of individual therapy, skills group training, and 24-hour access to telephone coaching. Members of the therapy team also attend weekly consultation meetings. In practice, many services offer DBT in varying intensities (e.g. skills group only) and durations. While individual psychotherapy focuses on enhancing client motivation for engagement and change, skills group focuses on developing new skills, which are broken up into four modules: Emotion Regulation, Distress Tolerance, Interpersonal Effectiveness and Mindfulness. Mindfulness forms part of all sessions for clients and members of the consultation team and is a key aspect of DBT. Treatment goals are hierarchically ordered, addressing life-threatening behaviours, therapy-interfering behaviours and quality of life-limiting behaviours (Linehan, Armstrong, Suarez, Allmon, & Heard, 1991).

Research has shown that DBT is linked with a reduction in the frequency and severity of non-suicidal self-harm, suicidal behaviours, psychiatric admission, improved therapy engagement, social adjustment and anger in individuals with Borderline Personality Disorder (Linehan et al., 1991; Linehan et al., 2006). DBT was hence recommended as a treatment for Borderline Personality Disorder by NICE in 2009.

Dialectical Behaviour Therapy, Bulimia Nervosa and Binge Eating Disorder

Some researchers have explored the effectiveness of standard DBT in the context of BN and BED, adding psycho-educational elements on eating disorders (Fischer & Peterson, 2014) or self-management skills (Kröger et al., 2010). Additionally, a manual for eating-disorder focused DBT has been published by Safer, Telch and Chen (2009). Eating-disorder-focused DBT consists of weekly 2-hour

group sessions that combine the functions of individual psychotherapy focused on enhancing motivation, and group-based skills-training, focused on learning emotion regulation skills. The Interpersonal Effectiveness module, which is part of standard DBT, is not included in eating-disorder-focused DBT. As in standard DBT, the treatment goals in eating-disorder-focused DBT are organised hierarchically, addressing therapy-interfering behaviours, abstinence from binge eating and purging and decreasing preoccupation with food, discounting of alternative behaviours and unhelpful behaviours such as buying binge foods (Telch, 1997). This in turn is thought to lead to healthier weight regulation and enhanced quality of life (Safer et al., 2009). Although weight is monitored, weight reduction is not a treatment target of eating-disorder-focused DBT.

Regardless of how DBT is implemented, mindfulness skills are taught from the start of therapy, as these are building blocks for other skills. Mindfulness involves bringing intentional, non-judgemental awareness to the present moment (e.g. focusing on breath) and noticing “events” (e.g. physical/emotional states) without reacting to them (Kabat-Zinn, 2003). Mindfulness underlies the ability to decide what “skilful” action to take instead of reacting automatically (Williams & Penman, 2011). Mindfulness and binge eating, which involves a loss of control and is linked with experiential avoidance (the avoidance of unwanted thoughts, feelings or sensations, regardless of the consequences), are hence incompatible (Lillis, Hayes, & Levin, 2011).

Three states of mind are introduced in the Mindfulness module: Reasonable Mind, characterised by rationality and logic; Emotion Mind, governed by emotional states; and Wise Mind. Wise Mind synthesizes Reasonable and Emotion mind but

also involves intuition (Linehan, 1993). The goal of mindfulness practice is to be better able to "be in" Wise Mind, which is thought to facilitate actions reflective of goals and values. Two sets of core mindfulness skills are taught (Safer et al., 2009); 'What' skills ('Observe', 'Describe' and 'Participate') guide access to Wise Mind and include exercises such as mindful eating (e.g. raisin-eating exercise) and Urge Surfing (observing and describing urges without reacting to them). 'How' skills (Nonjudgmentally, One-Mindfully and Effectively) guide the implementation of 'What' skills and include exercises such as Alternate Rebellion (e.g. eating the desired food mindfully or writing a letter to those who one wants to rebel against; Safer et al., 2009).

Published reviews

A limited number of published reviews have explored the effectiveness of mindfulness-based interventions such as DBT, Acceptance and Commitment Therapy and Mindfulness-based Cognitive Therapy in the context of clinical populations diagnosed with eating disorders (Manlick, Cochran, & Koon, 2013; Nunes-Costa, Lamela, & Gil-Costa, 2009; Wanden-Berghe, Sanz-Valero, & Wanden-Berghe, 2010). These literature and systematic reviews indicate that mindfulness-based interventions, including DBT, may be effective in reducing disordered eating behaviour, including binge eating frequency and severity, in individuals with BN, BED and Anorexia Nervosa (Nunes-Costa et al., 2009; Wanden-Berghe et al., 2010). In addition, a systematic review by Bankoff et al. (2012) indicated that DBT might be suitable for individuals with eating disorders and co-morbid Borderline Personality Disorder, reducing disordered eating behaviours, self-injury and anxiety/depression.

Two meta-analyses, exploring the effectiveness of mindfulness-based interventions including DBT in clinical and non-clinical populations of individuals with eating disorders have been published to date (Godfrey, Gallo, & Afari, 2015; Lenz, Taylor, Fleming, & Serman, 2014). Lenz et al. (2014) evaluated the effectiveness of DBT for reducing the number of binge eating episodes in adults with Anorexia Nervosa, BN or BED and co-morbid depression. Of the 11 identified studies, 9 were included in meta-analytic procedures, yielding large to very large effect sizes for the effectiveness of DBT to decrease eating disorder episodes (mean Cohen's *d* for between-group studies = 0.82, for within-group studies = 1.43). Medium to very large effect sizes for reducing co-morbid depression were identified (mean Cohen's *d* for between-group studies = 0.57, for within-group studies = 1.9). Significant heterogeneity was evident in all analyses; variation in sample size was identified as a moderating variable underlying this.

Similarly, Godfrey et al. (2015) carried out a systematic review and meta-analysis of mindfulness-based interventions for binge eating behaviour in clinical and non-clinical populations. While this included DBT, it also included approaches such as Acceptance and Commitment Therapy, mindfulness (e.g. Mindfulness-Based Eating Awareness Training, Mindfulness Based-Cognitive Therapy, Mindfulness-based Stress Reduction) and meditation. Combining 19 studies yielded large effects for a reduction in binge eating behaviours (mean within-group Hedge's *g* =-1.12, mean between-group Hedge's *g* =- .70). Nevertheless, within- and between-group heterogeneity was large (93% and 90%, respectively) suggesting that there was significant variation in methodological approaches between studies, which was not explored in any depth when attempting to interpret the results.

The current review: Rationale and aims

The ability to draw firm conclusions about the effectiveness of DBT to improve outcomes in individuals with BN and BED is limited by a lack of exploration of the effectiveness of DBT specifically, in individuals with sub- and full-threshold BN or BED, which have a distinct aetiology and profile that is different from Anorexia Nervosa. While most reviews included a small number of Randomised Control Trials, the bulk of the literature was made up of uncontrolled trials, often with small sample sizes, highlighting weaknesses in quality within the current evidence base (Wanden-Berghe et al., 2010). The application of comprehensive and robust quality criteria has been limited and the exploration of sources of heterogeneity has not been carried out systematically. More recently research with more rigorous experimental designs has emerged, suggesting that a review of the available literature that includes an exploration of sources of heterogeneity is warranted and may strengthen the evidence base for the use of DBT in BN and BED. This might encourage and guide further research exploring the applicability of DBT in the UK, potentially adding to the number of available treatment options in the long-term.

The current meta-analysis explored the therapeutic benefits of DBT on binge eating episode frequency in individuals with BN and BED; heterogeneity due to methodological factors was also explored.

Method

Search Strategy

A systematic search of the literature in PsychINFO, Medline and EMBASE databases was carried out in August 2017. The following search terms were used: “Dialectical Behaviour Therapy” [OR] “Dialectical Behavior Therapy” [OR] “DBT” [AND] “Eating Disorders” [OR] “Bulimia Nervosa” [OR] “Bulimia” [OR] “Binge Eating Disorder” [OR] “Binge Eating” [OR] “Binge*”, “Purge*”. The search included articles published between 1967 and the second week of August 2017. The initial search resulted in 261 papers. The search was re-run closer to the point of submission in March 2018, yielding no additional papers.

Inclusion and Exclusion Criteria

The primary trial papers were screened according to a number of inclusion and exclusion criteria. Exclusion criteria and their rationales are outlined in Table 1. Randomised Control Trials, non-randomised group comparisons and pre-post comparison studies were included. Although Randomised Control Trials are considered the ‘gold standard’ in study designs, only six were identified, reflecting the maturity of this area of research (NICE, 2012). The inclusion of non-randomised studies introduced a source of bias, which was addressed in the analysis and reflected on in the conclusions. To be included, papers had to report the effectiveness of DBT in the treatment of adolescents or adults with sub- or full-threshold BN or BED. Sufficient outcome data for binge eating behaviour (frequency of self-reported binge eating episodes) needed to be provided.

Table 1

Exclusion criteria used during the screening process

Exclusion Criteria	**Rationale**
Diagnosis. Individuals did not have a diagnosis of BN or BED/ did not meet full/sub-threshold criteria or BN or BED.	Individuals had to have a diagnosis of BN or BED or needed to meet full/sub-threshold criteria for BN or BED.
Type of Data. Unable to separate data reported for individuals with Anorexia Nervosa (AN) and BN/BED by diagnosis.	For articles that included samples made up of individuals with BN, BED and AN, outcome data for individuals with AN and BN/BED needed to be reported separately to allow drawing conclusions for individuals with BN/BED.
Summary Data. Authors did not report means and standard deviations or alternative statistical information (*t, F, Z* scores or *p*-values).	Adequate statistical information was required to allow the calculation of effect sizes for intervention and control groups and changes in pre-/post-intervention scores.
Duplicate data. Studies used the same dataset to explore different hypotheses.	The inclusion of duplicate data biases conclusions drawn on the basis of the meta-analysis.
Article Type. Books/book chapters, literature reviews, systematic reviews, theoretical papers, commentaries, clinical protocols, single and group case studies, case note reviews and 'grey literature' (e.g. unpublished doctoral theses) were excluded.	These types of publications do not provide the data or level of peer-review necessary and desirable for a meta-analysis.
Age. Samples were made up of individuals below the age of 14 years.	The meta-analysis focused on outcomes for adolescents aged 14 years or older and adults only.
English language. Articles were not available in English language.	Articles had to be written in English language, as there were only limited resources available to translate articles.
Comparison. Studies did not compare an active treatment group receiving a DBT intervention to a control group OR pre-intervention data was not compared to post-intervention data.	This type of comparison data is needed to analyse the effect of DBT on binge behaviour in individuals with BN or BED.
Outcome data. Studies did not report the frequency of self-reported binge eating episodes.	This type of comparison data is needed to analyse the effect of DBT on binge behaviour in individuals with BN or BED.

Selection of Studies

After the removal of duplicates, 178 articles were identified through the search of electronic databases. The titles and abstracts of papers were reviewed to establish their relevance to the review. This led to the exclusion of 153 articles. Reviewing the bibliographies of the remaining full-text articles yielded no further eligible trials. The application of the inclusion and exclusion criteria to papers led to the exclusion of 11 papers. Fourteen papers met all criteria and were included in the meta-analysis (see Figure 1).

An overview of the included papers can be seen in Table 2. Six studies were Randomised Control Trials; the remaining studies were active intervention group comparisons (*n*=1) or pre-post comparisons (*n*=7). Sample sizes varied widely between studies, ranging from seven to 98 participants. Three studies included adolescent samples, while the remaining studies explored the effectiveness of DBT in adults. There were variations in intervention duration and intensity, with some studies using standard DBT (*n*=4), individual therapy (*n*=1), group sessions (*n*=8) or guided self-help (*n*=1). Although most studies were carried out in outpatient settings, Kröger et al. (2010) carried out research in an inpatient setting and Murray et al. (2015) in an outpatient and hospital setting. The main outcome, binge eating episode frequency, was most frequently measured using the Eating Disorder Examination (EDE; Fairburn & Cooper, 1993); few studies used a combination of the Questionnaire for Eating Disorder Diagnosis (Q-EDD; Mintz, O'Halloran, Mullholland, & Schneider, 1997) and diary cards, single item measures or measures exploring overall binge eating severity (Binge Eating Scale; Gormally, Black, Daston, & Rardin, 1982).

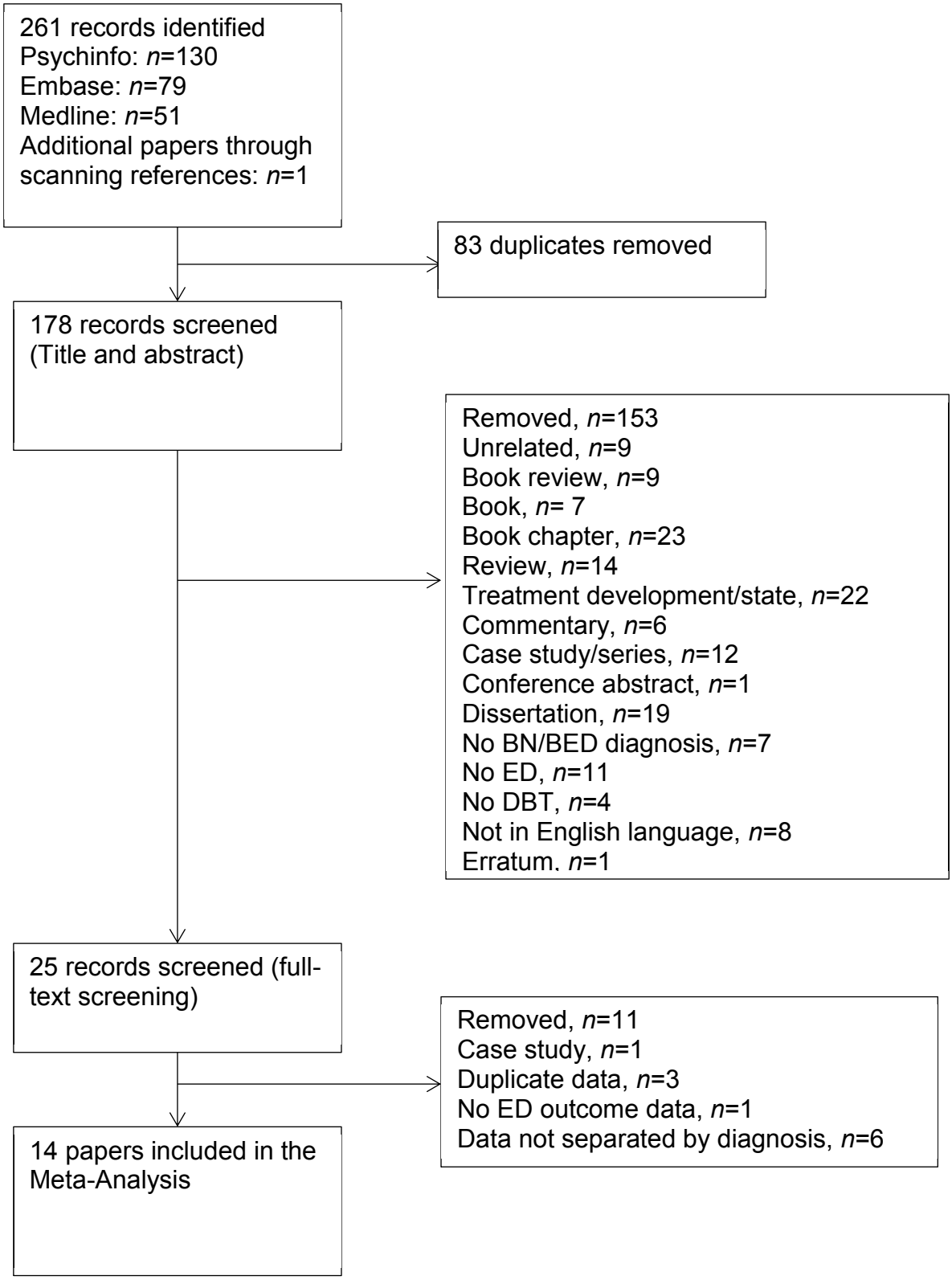

Figure 1. Overview of the process of identification and selection of articles for the review

Table 2

Overview of the included papers and study characteristics. The information is further broken down by intervention (IG) and control group (CG) where appropriate

Study	Trial Type	*N* DBT	*N* CG	Age (*M*)	Diagnosis	Control Group	Intervention duration and intensity	Outcome measure
Chen et al. (2017)	RCT	36	42	38.2	BN and BED	Continued Guided self-help	6 months weekly skills group (2h) Weekly individual therapy (1h) 24h telephone coaching	EDE[2]
Fischer & Peterson (2014)	Pre-Post Comparison	7	N/A	16.2	BN/ Eating Disorders Not Otherwise Specified	-	6 months weekly skills group (?h) weekly individual therapy (?h) 24h telephone coaching (?h) 6-month parent group (?h)	EDE
Hill, Craighead, & Safer (2011)	RCT	18	14	21.87	BN	Waiting list (delayed treatment control)	3 months weekly group sessions (6 sessions 1.5h, 6 sessions 1h)	EDE
Klein, Skinner, & Hawley (2012)	Pre-Post Comparison	10	N/A	39.6	BN and BED	-	4.5 months 16 weekly group sessions (2.5h) 24h telephone coaching	Q-EDD[3]
Klein, Skinner, & Hawley (2013)	Active intervention Group Comparison	22	14	33.05	BN and BED	Diary Cards 15 individual sessions over 16 weeks (0.25h)	4 months 1 individual orientation session (1.5h) 15 weekly group sessions (2.5h) 24h telephone coaching	Q-EDD
Kröger et al. (2010)	Pre-Post Comparison	15	N/A	31.1[1]	BN	-	3 months weekly individual therapy (1h) 3 weekly group sessions (1.5h)	BEE[4]
Masson, von Ranson, Wallace, & Safer (2013)	RCT	30	30	42.8	BED	Waiting list	3.25 months 1 orientation session (0.75h) 6 bi-weekly support phone calls (0.3h)	EDE

Study	Trial Type	*N* DBT	*N* CG	Age (*M*)	Diagnosis	Control Group	Intervention duration and intensity	Outcome measure
Mazzeo et al. (2016)	Pre-Post Comparison	12	N/A	15.42	BED	-	2.5 months weekly group sessions (1.5h)	EDE
Murray et al. (2015)	Pre-Post Comparison	35	N/A	15.7	BN	-	2 months Individual & family therapy Parent-only group sessions Multi-family meals, parent only components (3-10h per day)	EDE
Mushquash & McMahan (2015)	Pre-Post Comparison	11	N/A	44.56	BED	-	2.5 months weekly group sessions (2h)	BES[5]
Safer, Telch, & Agras (2001)	RCT	14	15	34	BN	Waiting list	5 months weekly individual therapy (0.83h)	EDE
Safer, Robinson, & Jo (2010)	RCT	50	48	52.2	BED	Active Comparison Control Group (manualised, based on treatment for chronic depression)	5 months weekly group sessions (2h)	EDE
Telch, Agras, & Linehan (2000)	Pre-Post Comparison	11	N/A	45	BED	-	5 months weekly group sessions (2h)	EDE
Telch, Agras, & Linehan (2001)	RCT	18	16	50	BED	Waiting list	5 months weekly group sessions (2h)	EDE

[1]Average age of the total sample (BN and AN combined)
[2]Eating Disorder Examination (EDE; Fairburn & Cooper, 1993)
[3]Questionnaire for Eating Disorder Diagnosis (Q-EDD; Mintz, O'Halloran, Mullholland, & Schneider, 1997) at baseline, Diary Cards at time 2
[4]Single item exploring the frequency of binge eating episodes over the last month (BEE; Kröger et al., 2010)
[5]Binge Eating Scale (BES; Gormally, Black, Daston, & Rardin, 1982)

Table 3 shows the summary data and effect sizes (Cohen's *d*) of the studies included in this meta-analysis. It was common for studies to report outcomes for changes in binge eating episode frequency based on pre-post intervention comparisons and differences in binge eating episode frequency between individuals receiving DBT or a control intervention/placed on a waiting list. The majority of studies reported reductions in binge eating episode frequency over time or between groups as a result of a DBT intervention.

Table 3

Summary data and effect sizes for binge eating outcomes reported in studies included in this meta-analysis

Study	**Binge episodes pre-intervention/Control Group (*M, SD*)**	**Binge episodes post-intervention/DBT (*M, SD*)**	**Cohen's *d***
Chen et al. (2017)	3.13 (7.81)	6.53 (16.42)	0.27
Fischer & Peterson (2014)	9.29 (8.9)	4.57 (11.19)	-0.47
Hill, Craighead, & Safer (2011)	9.5 (5-40)[1]	4 (0-50)	-0.97[2]
Klein, Skinner, & Hawley (2012)	3.4 (1.78)	.5 (.58)	-2.68
Klein, Skinner, & Hawley (2013)	1.64 (1.62)	0	-0.74
Kröger et al. (2010)	36.87 (9.14)	10.33 (4.43)	-3.7
Masson, von Ranson, Wallace, & Safer (2013)	14.37 (11.86)	5.97 (9.42)	-0.79
Mazzeo et al. (2016)	2.53	1.74	-1.11
Murray et al. (2015)	4.03 (6.69)	1.43 (3.66)	-0.48
Mushquash & McMahan (2015)	28.72 (4.88)	22.06 (7.79)	-0.87
Safer, Telch, & Agras (2001)	20	1.5	-0.87
Safer, Robinson, & Jo (2010)	5	1.8	-2.01
Telch, Agras, & Linehan (2000)	15.2 (12.3)	3.2 (7.6)	-1.17
Telch, Agras, & Linehan (2001)	10 (14)	0	-2.15

[1]Median (Range, if available)
[2]Comparison at 6 weeks

Quality Framework

The risk of bias in the selected studies was evaluated through the application of a quality framework that was specifically developed for and tailored to the requirements of this meta-analysis. Published quality frameworks such as the Cochrane Collaboration Risk of Bias Tool (Higgins et al., 2011), the Risk of Bias Assessment Tool for Nonrandomised Studies (RoBANS) (Kim et al., 2013) and a framework developed by Downs and Black (1998) guided its development. The resultant quality framework was applied to each study and assessed risk of bias on seven domains: Selection Bias, Treatment Fidelity, Detection Bias, Statistical Bias, Methodological Bias, Measurement Bias and Reporting Bias (Table 4). Each domain was evaluated by one or more item(s), rated on a 3-point Likert scale ranging from 0 (*Low Risk*) to 2 (*High Risk*). Subsequently, each study was evaluated on the basis of 12 items.

Table 4

Overview of risk of bias domains and sub-items of the quality framework developed for this meta-analysis

Risk Domain	Explanation	Rating	Description of Rating
Selection Bias	1. Allocation of participants to a control group or DBT group was reportedly random, partially random or not random. If allocation was random the randomisation process is clearly described. This does not apply to studies with a within-subjects design.	0	Participants randomly assigned to an intervention and control condition. Process clearly described.
		1	Allocation partly randomised and/or process not described
		2	Allocation non-random or foreseeable
		N/A	Study has a within-subject design
Treatment Fidelity	2. Adherence to treatment protocols is monitored and reported on.	0	It is reported how treatment adherence was measured and how well manuals were adhered to
		1	It is reported how fidelity was assessed but no comment on how well therapists adhered to the manual was made
		2	No comment on how adherence to treatment manuals was assessed or how well researchers adhered to these was made.
Detection Bias	3. Awareness of individuals carrying out outcome assessments at varying time points of the treatment allocation of participants.	0	Blinding of researchers carrying out outcome assessments is reported and they are separate from therapy team
		1	Outcome assessments carried out by researchers who are separate from the therapy team but blinding is unclear
		2	Outcome assessments carried out by therapy team
Statis-tical Bias	4. Appropriate analyses selected to analyse data and to manage impact of attrition.	0	No or very low attrition and appropriate analyses selected
		1	Low attrition with completer or ITT analyses reported, non-completers described
		2	High attrition and only completer analyses reported
Methodological Bias	5. Recruitment: Means and reach of recruitment.	0	Participants were recruited via multiple means such as newspaper ads, flyers and clinic referrals reaching a wide range of potential participants
		1	Recruitment via limited means but reaching out further than one site
		2	Recruitment via one means only (e.g. referral) from one site only or recruitment insufficiently described.
	6. BMI: Reporting of BMI.	0	BMI (mean and SD) reported
		1	Insufficient information on BMI reported
		2	BMI not reported
	7. ED Diagnosis: Reporting of ED diagnosis and relevant criteria and proportion of sample meeting full or sub-threshold criteria.	0	Criteria for BN/BED diagnosis and proportion of sample meeting full- or sub-threshold criteria reported
		1	Criteria unclear, but proportion of sample with BN/BED reported
		2	Criteria unclear and proportion of sample with BN/BED not reported
	8. ED Duration: Reporting of the duration of the ED participants had been diagnosed with and differences in this between DBT and control groups (for between subjects studies only).	0	ED duration (mean and SD) reported
		1	Insufficient information on ED duration provided
		2	ED duration not reported
	9. Co-morbidities: Reporting of co-morbidities participants presented with and whether or not these were a reason for exclusion.	0	Some excluded and remaining co-morbidities reported
		1	Some excluded but remaining co-morbidities not reported
		2	Comorbidities not reported, no groups excluded
	10. Sample Size.	0	60+ participants
		1	30 to 60 participants
		2	Less than 30 participants
Measure-ment Bias	11. Reporting of the type and validity of the outcome measure used.	0	Binge eating frequency was measured in a standardised using a validated tool, reliability reported
		1	Binge eating frequency was measured in a standardised way but the tool was not validated and/or its reliability was not reported
		2	Binge eating frequency was not measured in a standardised way, the measure was not validated and reliability was not reported.
Reporting Bias	12. Reporting of pre-specified outcomes.	0	Sufficient data on all pre-specified outcomes is reported
		1	Some data on pre-specified outcomes is missing or not clearly reported
		2	Reported outcomes do not correspond to pre-specified outcomes

Quality Ratings

An overall quality rating was calculated for each study. Studies could score a maximum of 24 points. Points were deducted for unclear (1 point) and high (2 points) risk ratings. Lower scores indicate a greater risk of a study being affected by bias. Scores ranged from 10 to 19.

Two studies with a within-subject design and small sample sizes showed the greatest risk of bias (Mazzeo et al., 2016; Mushquash & McMahan, 2015. A common risk of bias was that many studies failed to report treatment adherence and its measurement. The allocation of risk of bias to the primary studies is summarised in Table 5.

Table 5

Overview of risk of bias ratings based on the application of the quality framework developed for this meta-analysis

	Selection Bias	Treatment Fidelity	Detection Bias	Statistical Bias	Methodological Bias						Measure-ment Bias	Reporting Bias	Quality Index
Study	1	2	3	4	5	6	7	8	9	10	11	12	
Chen et al. (2017)													15
Fischer & Peterson (2014)													17
Hill et al. (2011)													17
Klein et al. (2012)													11
Klein et al. (2013)													13
Kröger et al. (2010)													13
Masson et al. (2013)													17
Mazzeo et al.(2016)													10
Murray et al. (2015)													12
Mushquash & McMahan (2015)													10
Safer et al. (2001)													17
Safer et al. (2010)													19
Telch et al. (2000)													17
Telch et al. (2001)													18

High risk = Unclear risk = Low risk = N/A =

Quantitative Synthesis

Meta-Analytic Model. A meta-analysis was conducted for binge eating episode frequency, using the R Software "Meta" and "Metafor" package (Schwarzer, 2007; Schwarzer, Carpenter, & Rücker, 2015; R Core Team, 2015). The meta-analytic effect of DBT for reducing the number of binge eating episodes was calculated using a random-effects model. This model was selected for a number of reasons.

Firstly, the random-effects model assumes that effect sizes between different studies vary and that the included effect sizes merely represent a random sample of all possible observable effect sizes. In a random effects model the summary effect hence describes an estimated mean of the true effect size. By contrast, fixed-effects models assume that the effect size is equal in all included studies, with the summary effect representing this common effect size (Borenstein, Hedges, Higgins, & Rothstein, 2009). As can be seen in Table 3, effect sizes vary widely between the selected studies, suggesting that the use of a random-, rather than a fixed-effects model, is more appropriate.

Secondly, while fixed-effects models consider only within-study error, random-effects models additionally take between-study error into account. This is an important difference between the two models as it means that the variance associated with the summary effect will be larger in a random- compared to a fixed-effects model. The studies included in the current meta-analysis were carried out by different researchers/research groups, treatment protocols differed and therapists potentially varied in their interpersonal styles, therapy skills and application of treatment manuals. It is hence crucial to account for between-study variation in the present meta-analysis.

Identifying the Impact of Methodological Quality. A quality effects model was reported in addition to the random-effects model. The quality effects model calculates a random-effects model in which the primary studies are weighted by both their sample size and their rating for risk of methodological bias. Accordingly, the quality effects model yields a meta-analytic effect that accounts for methodological variation and the impact of bias.

Quantifying and Exploring Heterogeneity. Heterogeneity in the current meta-analysis was explored using Cochrane's *Q*, Higgins I^2 and Tau^2. High levels of heterogeneity indicate that the relationship between DBT and binge eating episode frequency may be influenced by uncontrollable factors such as methodological variation in primary studies. In such cases it would be misleading to use the combined effect size and to draw conclusions about the meta-analytic effect. Meta-regression and subgroup analyses will be used to explore the underlying cause of heterogeneity (Jüni, Altman, & Egger, 2001).

Cochrane's *Q* gives an estimation of the deviation of each effect size from the mean of all studies, while Tau^2 is an additional measure of between-study variance. Higgins I^2 is a measure of the proportion of the total variance that is attributable to the variation in true effect sizes. Higgins, Thompson, Deeks, and Altman (2003) suggest that a Higgins I^2 of 25% indicates low heterogeneity, of 50% indicates moderate heterogeneity and of 75% high heterogeneity. In the case of low or moderate heterogeneity the purpose of a meta-analysis is to estimate the distribution of the true effects. However, when heterogeneity is high it is likely that the observed levels of variation have been inflated by uncontrolled methodological factors, and therefore further exploration of the causes of variation may be undertaken using

meta-regression and subgroup analysis (see Appendix C for potential sources of heterogeneity identified a priori).

Identifying Influential Studies. The impact of influential studies was explored using the “one left out” procedure. This approach involves the systematic omission of each primary study to explore whether an individual study has a disproportionate impact on the estimate of the overall effect (Dias, Sutton, Welton, & Ades, 2011). If the estimate of the overall effect substantially changes as a result of the omission of a particular study then it may be concluded that study in question is having a disproportionate influence on the overall analysis. In situations where the study in question is reporting effects inconsistent with the other studies in the meta-analysis its influence may be considered as bias.

Publication Bias. Publication bias reflects the tendency for research showing null effects not to be published. Therefore, even if all relevant published articles were included in the current meta-analysis, this systematic bias in publication will impact on the accuracy of this review. The presence of publication bias was explored by visual inspection of funnel plots and supplemented by the calculation of a statistical measure of plot asymmetry (Egger, Smith, Schneider, & Minder, 1997); if publication bias is suspected its impact can be estimated using a “Trim and Fill” procedure (Duval & Tweedie 2000a, 2000b).

Results

Meta-analysis

A total of 14 studies with 343 participants explored differences in binge eating episode frequency between individuals receiving DBT or no intervention/a control intervention or changes in binge eating episode frequency from baseline to follow-up in individuals with sub- or full-threshold BN or BED. Figure 2 shows that the random-effects model yielded a very large, significant effect, indicating that individuals receiving DBT compared to those in a control group engaged in fewer binge eating episodes and that there was a reduction in binge eating frequency for those who were compared before and after receiving DBT.

Identifying the Impact of Methodological Quality

A random-effects model weighed by methodological quality was generated. This model estimates the meta-analytic effect, assuming that all the included studies are of high methodological quality. The model demonstrated that effects were robust (*SMD*=-1.22, 95% *CI*[-1.7, -0.73]), estimating that the observed effect would have been slightly larger if all included studies had been of good methodological quality.

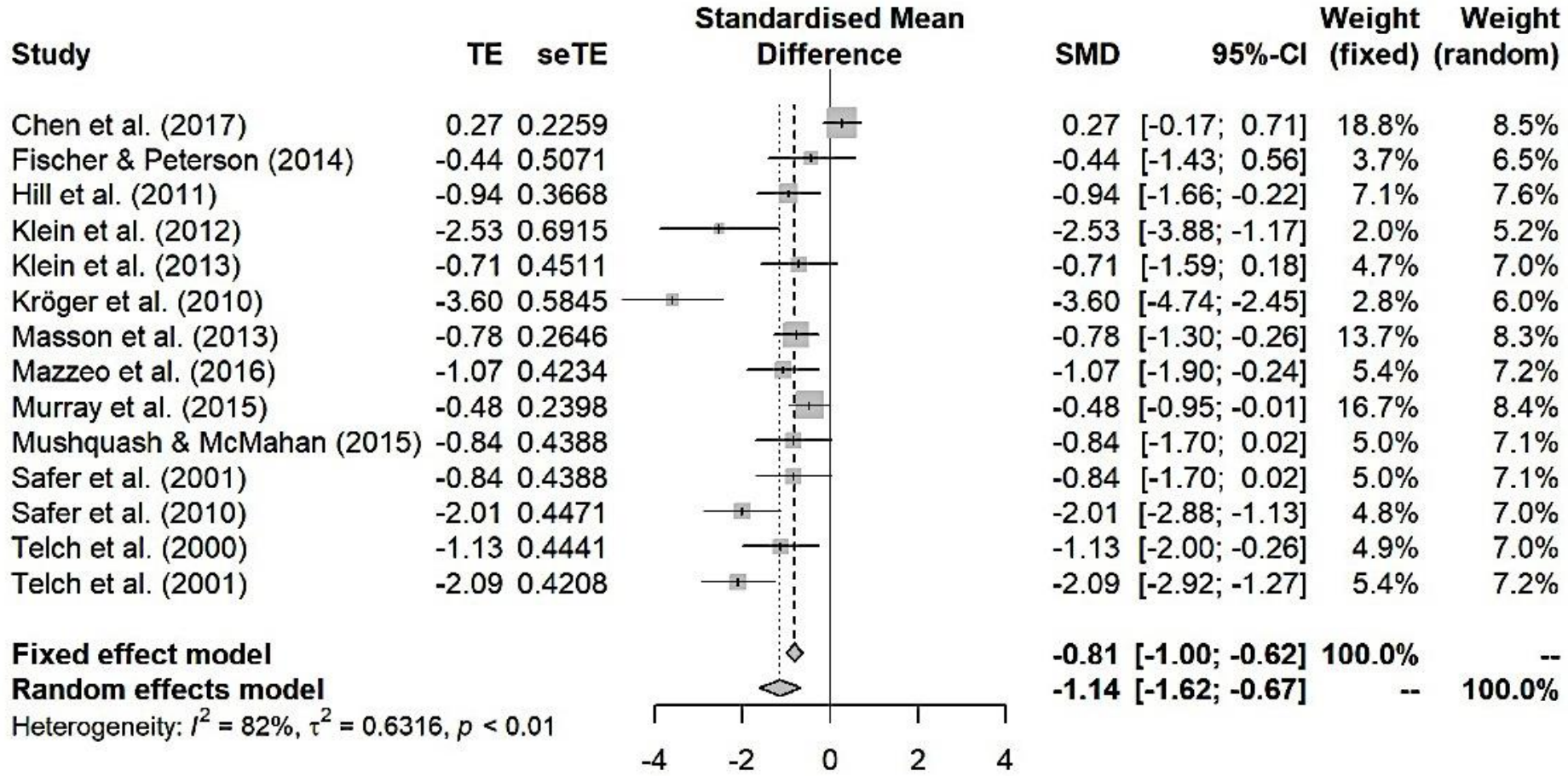

Figure 2. Forest plot for frequency of binge eating episodes

Quantifying and Exploring Heterogeneity

Higgins I^2 indicated that 81.9% of the total variation in binge eating episode frequency was explained by heterogeneity due to variations in methodological quality between studies. Due to the large amount of heterogeneity significance testing of the combined effect size may not be meaningful. Moderation analyses were hence carried out to explore this further. Meta-regression can be used to identify whether unexplained variation in effect sizes can be attributed to uncontrolled methodological factors measured as continuous variables; subgroup analysis can be used to assess the impact of categorical variables on unexplained heterogeneity. Meta-regression indicated that none of the potential continuous moderators had a significant impact on the meta-analytic effect (Table 6).

Table 6

Estimated difference of meta-analytic effect due to moderating effects of methodological variation in continuous variables explored through meta-regression

Moderator	**Regression estimate (*b*)**	***z*-value**	***p*-value**
Sample Size (*n*=14)	.01	.52	.52
Age (*n*=14)	-.02	-1.09	.23
Ethnicity (*n*=14)	-2.23	-1.43	.15
BMI (*n*=11)	-.01	-.14	.89
Full-Threshold (*n*=12)	-.47	-.54	.59
Eating Disorder Duration (*n*=6)	-.03	-.66	.51
Intervention Intensity (h p/w; *n*=13)	-.19	-1.07	.28
Intervention Duration (*n*=14)	.08	.44	.67
Publication Year	.06	1.65	.10

The subgroup analysis revealed that family involvement and therapist team qualification/composition significantly explained some of the observed heterogeneity (Table 7). It is noted that studies that did not include families in the therapeutic process yielded larger meta-analytic effects than studies with family involvement (Figure 3) and that studies that delivered the DBT intervention via mixed therapist teams (including masters level therapists and doctoral level clinical psychologists) yielded the largest meta-analytic effect (Figure 4). However, for both family involvement and therapist team qualification/composition, the small number of primary studies in the subgroups confounds an estimation of the moderator.

Table 7

Estimated difference of meta-analytic effect due to moderating effects of methodological variation in categorical variables explored through subgroup analysis

Subgroup	***SMD***	**Outcome**
Study Design	Between-Subject Design (*n*=7): -.98 Within-Subject Design (*n*=7): -1.34	*Q*(1)=53, *p*=.47
Trial Type	RCT (*n*=6): -1.02 Pre-Post Comparison (*n*=7): -1.34 Uncontrolled Pre-Post Comparison (*n*=1): -.71	*Q*(2)=1.19, *p*=.55
Diagnosis	BN (*n*=5): -1.18 BED (*n*=6): -1.28 Both (*n*=3): -.86	*Q*(2)=.32, *p*=.85
Borderline Personality Disorder	Yes (*n*=3): -2.23 No (*n*=2): -1.54	*Q*(1)=.37, *p*=.54
Psychotropic Medication	Yes (*n*=6): -1.18 No (*n*=3): -1.36	*Q*(1)=.09, *p*=.76
Concurrent Therapy	Yes (*n*=1): -1.38 No (*n*=9): -2.53	*Q*(1)=2.39, *p*=.12
Outcome Measure	Eating Disorders Examination (*n*=9): -.89 Other Outcome Measure (*n*=5): -1.68	*Q*(1)=1.82, *p*=.18
Intervention Mode	Standard DBT (*n*=4): -.96 Group DBT (*n*=6): -1.33 Group, Telephone Coaching (*n*=2): -1.54 Guided SH (*n*=1):-.78 Individual DBT (*n*=1): -.83	*Q*(4)=3.17, *p*=.53
Payment for Therapy	Yes (*n*=2): -1.54 No (*n*=12): -1.1	*Q*(1)=.22, *p*=.64
Family Involvement	Yes (*n*=2): -.47 No (*n*=12): -1.28	*Q*(1)=5.08, *p*=.02
Therapist Team Qualification/ Composition	Masters Level Qualification (*n*=1): .27 Doctoral Level Qualification (*n*=5): -1.22 Mixed Therapist Team (*n*=5): -1.69	*Q*(2)=21.77, *p*<.0001

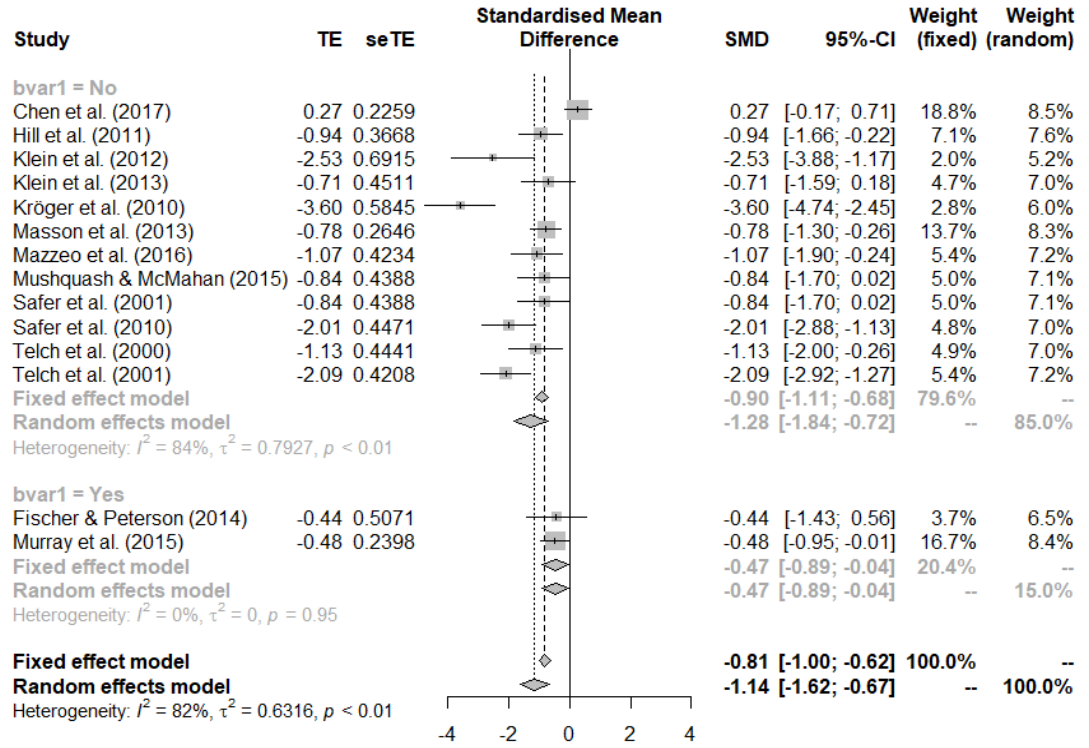

Figure 3. Forest plot of subgroup analysis for family involvement

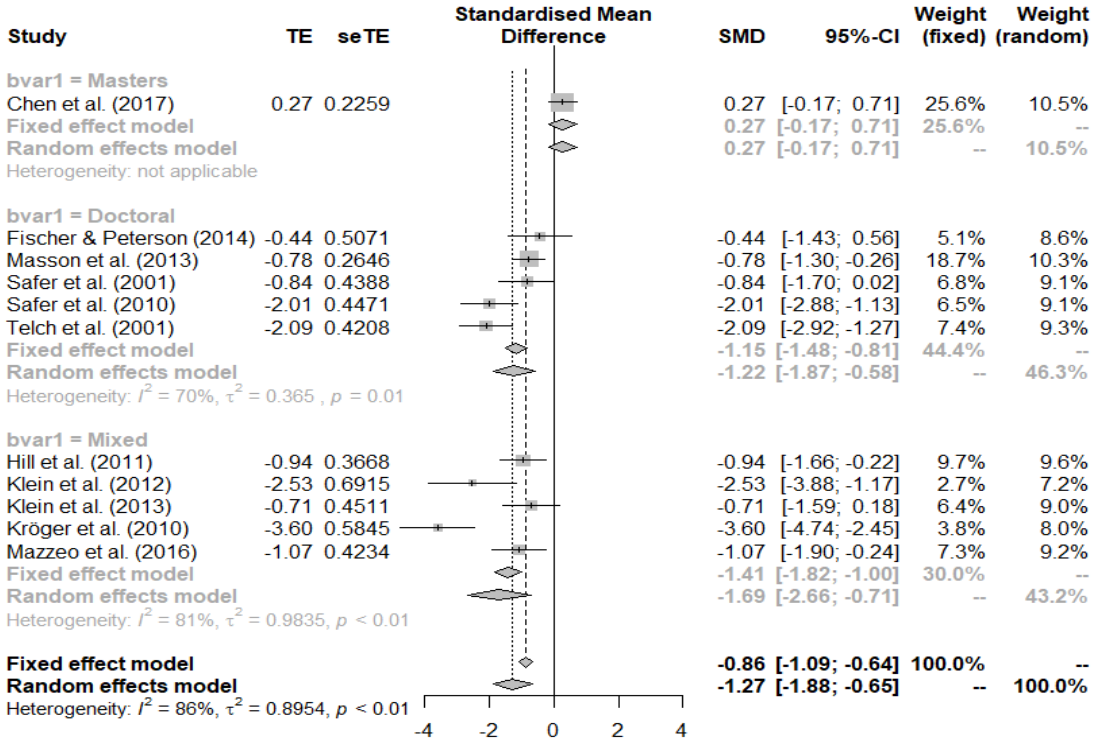

Figure 4. Forest plot of subgroup analysis for therapist team qualification/composition

Identifying Influential Studies

Figure 5 shows that the omission of any individual study did not lead to a significant change in the overall meta-analytic effect. This indicates that no individual study has a disproportionate impact on the observed effect.

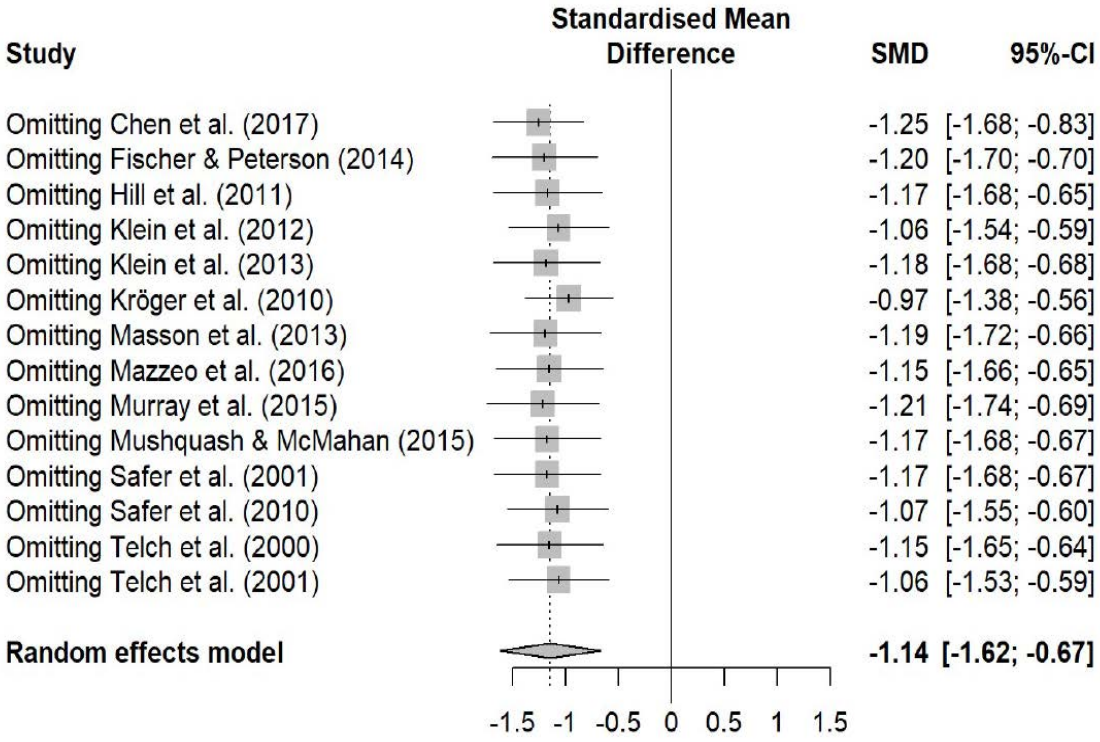

Figure 5. Forest plot highlighting the impact of individual studies on the meta-analytic effect for binge eating frequency

Publication Bias

The relationship between effect size and sample size is graphically represented in the funnel plot (Figure 6). It is likely that less precise, smaller studies yield larger variation in effect sizes. The triangular zone of the funnel plot represents the 95% confidence interval for the distribution of effect sizes in an unbiased literature. Assuming the absence of biases, a symmetrical distribution of effect sizes across the funnel plot is expected. Unfortunately, the funnel plot of the data evidenced considerable asymmetry (Egger=-5.39, p=.002), with four small studies with large effect sizes falling outside of the 95% confidence interval.

To estimate the impact of publication bias, the “Trim and Fill” procedure was applied (Duval & Tweedie, 2000a, 2000b). This procedure involves the removal of extreme studies and the addition of estimated, unpublished studies, which is achieved by the “mirroring” of existing studies until sufficient symmetry in the funnel plot is achieved (Duval & Tweedie, 2000a, 2000b). Six studies were added into the analysis to control for publication bias. This resulted in a reduction of the summary effect by approximately 53%; with correction for publication bias, the summary effect was *SMD*=-0.51 (95% CI[-1.01; .0007], p=.05). This suggests that correction for publication bias resulted in a marked reduction in the estimate of the summary effect, but that this effect remained statistically significant.

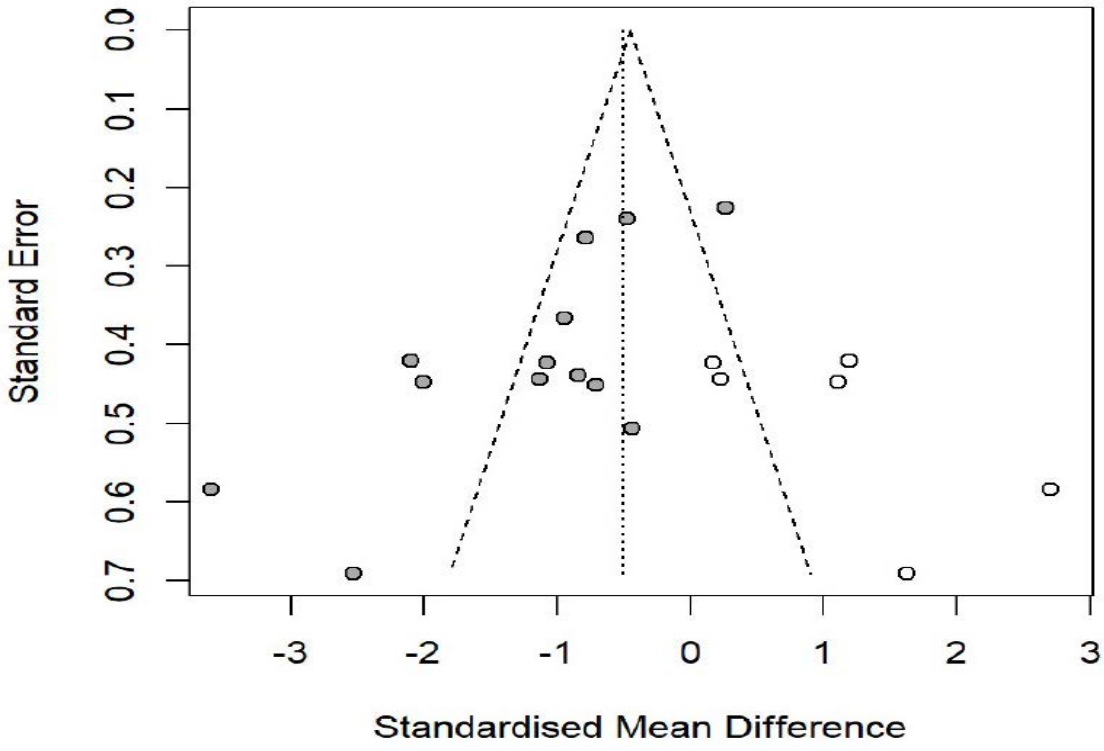

Figure 6. Funnel plot following “Trim and Fill” procedure. Empty circles indicate simulated studies

Discussion

Summary of the Findings

The meta-analysis explored the direction and magnitude of the effect of DBT on binge eating episode frequency in individuals with sub- and full-threshold BN and BED and evaluated the impact of potential sources of heterogeneity systematically. The results of the meta-analysis, which included data from 14 studies, indicate very large effects of DBT on binge eating episode frequency, showing a significant reduction in episodes following engagement in DBT and in those engaging in DBT compared to those in control groups. To translate the effect size into frequency values for binge eating episode reduction the standard deviations for each relevant outcome measure need to be combined and weighed by their impact on the overall meta-analytic effect. The quality effects model did not significantly attenuate the results, indicating that if the methodological quality of studies were improved, the observed effect would have been slightly larger. The recalculation of the meta-analytic effect under exclusion of individual studies indicated that effects were robust and not driven by individual papers. There was some evidence that publication bias may have inflated the observed effect. The results suggest that if the methodological quality of studies was improved, and unpublished null studies were included, the true meta-analytic effect would fall between -1.22 and -.51. Currently, the best estimate of the impact of DBT on binge eating episode frequency in individuals with full- and sub-threshold BN or BED is -1.14.

The results of the current meta-analysis are similar to reviews by Godfrey et al. (2015) and Lenz et al. (2013). In both meta-analyses medium to very large effects of mindfulness-based interventions including DBT on binge eating episode frequency

in individuals with eating disorders with and without co-morbidities were reported. Both reviews commented on the significant heterogeneity in the data, which was also seen in the current meta-analysis, highlighting that the testing and interpretation of the combined effect size needs to be regarded with caution (Jüni et al., 2001).

Variation in Effects and Moderators

While Godfrey et al. (2015) did not explore sources of heterogeneity, Lenz et al. (2013) inspected the effect sizes of studies, concluding that variations in sample size were likely to underlie heterogeneity. Meta-regression and subgroup analyses were carried out in the current meta-analysis to explore sources of heterogeneity systematically. These analyses indicated that family involvement in therapy and the therapist team qualification and composition had a significant impact on the variability in the observed effects.

Involving families in the treatment of eating disorders can have a significant impact on outcomes, improving treatment gains and family relationships (Le Grange, Lock, Agras, Bryson, & Jo, 2015). Interestingly, studies that did not involve family members in the therapy process yielded larger effect sizes than studies that did. These findings have to be regarded with caution, as only two of the studies included involved family members, both with small sample sizes (N=7 and N=35), and each engaged family members in therapy processes differently (Fischer & Peterson, 2014; Murray et al., 2015). Fischer and Peterson's (2014) study offered a 6-month standard DBT intervention to adolescents; parents only attended one individual therapy session per month with their children and were invited to a parent skills group. Nevertheless, attendance at this was poor and the authors highlighted that opportunities for more intensive family therapy would have been desirable. Murray et

al. (2015) integrated DBT and family-based approaches in a partial hospital treatment programme that varied in duration and intensity. Parents attended family therapy with their child and engaged in multi-family and parent-only components. Significant reductions in binge eating episode frequency were observed in both studies but the lack of control groups limits our ability to draw conclusions about the impact of family involvement in DBT. Overall, the results indicate the integration of DBT and family-based approaches in the context of eating disorders requires further exploration.

The qualification of therapists and the composition of the therapy team also significantly moderated the meta-analytic effect. Studies using mixed therapist teams with masters and doctoral level training yielded larger effect sizes than studies using either doctoral or masters level therapists. As before, these findings need to be considered with caution as sample sizes were small and only one of the included studies used Master level therapists (Chen et al., 2017). Studies exploring the impact of therapist training on treatment outcomes are sparse, suggesting that effects on outcomes are modest (Miller & Binder, 2002). Research has indicated that training novice therapists in standardised treatment protocols increases their adherence to techniques but treatment outcomes appear to be more accurately predicted by therapist competence (Multon, Kivlighan, & Gold, 1996). More junior, Masters level therapists potentially adhered to treatment manuals more strictly, while more experienced therapists may have been particularly skilled in developing positive therapeutic relationships and alliances, which are crucial for therapeutic change (Hellerstein et al., 1998). The combination of treatment protocol adherence and use of techniques in combination with clinical experience may hence explain this result.

Further research exploring therapist effects and the influence of training on the fidelity with which DBT is delivered and the impact on treatment outcomes is needed.

Methodological Issues

DBT delivery. Many of the included studies differed in the delivery of DBT but maintained its basic structure and use of strategies, teaching mindfulness, emotion regulation and distress tolerance skills; some also included skills related to the interpersonal effectiveness module (Chen et al., 2017; Fischer & Peterson, 2014; Kröger et al., 2010; Mazzeo et al., 2016; Murray et al., 2015; Mushquash & McMahan, 2015). The impact of variations in therapy mode, intensity and duration were explored using sensitivity analyses, indicating that these factors did not impact on the meta-analytic effect. Nevertheless, in many studies there was no or limited information on how treatment fidelity was measured and what level of fidelity was obtained. While treatment fidelity was not mentioned in seven studies, six studies assessed fidelity by reviewing audio- or video-recorded sessions (Kröger et al., 2010; Mazzeo et al., 2016; Safer et al., 2010), in vivo observation of sessions (Fischer & Peterson, 2014), or self-report ratings (Hill et al., 2011). However, little information on fidelity ratings was reported. Only Masson et al. (2013) assessed treatment fidelity by rating audio-recordings and reported that questions were asked in accordance with the treatment manual 98.9% of the time. Previous research has indicated that treatment protocol adherence is positively associated with outcomes and it would have been interesting to explore its impact on the overall meta-analytic effect (Barber, Crits-Christoph, & Luborsky, 1996; Miller & Binder, 2002). More information on treatment fidelity and reflections on its impact on outcomes should be included in future publications.

Blinding of outcome assessors. Information on the blinding of outcome assessors was inconsistently provided. Only three of the included studies highlighted that assessors were blind to participants' allocation (Hill et al., 2011; Klein et al., 2013; Masson et al., 2013), suggesting that detection bias could inflate the observed meta-analytic effect (Jüni et al., 2001).

Control groups. In many of the primary studies the lack of a control group limited the ability to draw strong conclusions about the effectiveness of DBT, and studies comparing DBT to other active interventions are scarce (Safer, Robinson, & Jo, 2010). This reflects the relative maturity of this research area. The impact of confounding variables is hence likely to play a role in the observed effects. Well-designed methodologically robust studies including control groups with large samples are needed to increase confidence in the proposed effectiveness of DBT for decreasing binge eating episode frequency.

Generalisability. Most studies had small, homogenous samples consisting of female, Caucasian participants from the USA, Canada and Germany. This makes it difficult to generalise the present findings to males and individuals with different ethnic and cultural backgrounds. Research has suggested that the strength of the relationship between body image dissatisfaction and BED differs for males and females, and that females express more guilt and shame in the context of binge eating episodes (Grilo & Masheb, 2005; Lewinsohn, Seeley, Moerk, & Striegel-Moore, 2002). Furthermore, research has suggested that there are differences in body image preferences, treatment seeking and engagement in individuals from different ethnic backgrounds (Mazzeo et al., 2016). This suggests that subtle variations in intervention foci and modules may impact positively on outcomes for

males and females and those with different ethnic backgrounds. The presence of specific comorbidities, the use of psychotropic medication and concurrent therapy as well as the duration of eating difficulties were often not clearly reported, but these factors are likely to have an impact on the effectiveness of DBT (e.g. Walsh et al., 1997). Researchers should therefore continue to explore the effectiveness of DBT in diverse samples while taking care to clearly report sample characteristics, which may impact on outcomes. This will help clinicians to select intervention approaches most suitable to their clients' needs.

Follow-up data. Few studies provided clear follow-up data (ranging from three to 15 months) and this could hence not be evaluated in the current meta-analysis (Chen et al., 2017; Fischer & Peterson, 2014; Kröger et al., 2010; Masson et al., 2013; Telch et al., 2001). Nevertheless, an exploration of long-term effects and whether any improvements in binge eating episode frequency can be maintained some time after engaging in DBT would be crucial to make recommendations about its use in services.

Limitations of the Meta-analysis and Recommendations for Future Research

The small number of included studies limited the power to detect differences and the ability to draw firm conclusions from this meta-analysis. This is particularly relevant in the context of controlling for publication bias, which resulted in a reduction of the overall meta-analytic effect. Due to the strict inclusion and exclusion criteria, focusing on higher-quality research designs, excluding case studies and series, limited the pool of eligible studies. Nevertheless, it was felt that strict criteria were necessary to address the aims of this meta-analysis.

A further limitation of this meta-analysis is that, in many cases, groups in the subgroup analyses only consisted of a small number of studies, increasing the risk of reporting significant effects due to individual studies carrying larger weight (Kröger et al.; Klein et al., 2012). These analyses hence need to be regarded with caution. Nevertheless, exploring the impact of potential moderators on the meta-analytic effect provided some interesting insights into factors requiring further consideration to improve the effectiveness of DBT.

Only few studies added self-management skills or appetite awareness training to DBT and eating-disorder-focused DBT. The addition of these skills may have impacted on the observed outcome. This was not explored in the current meta-analysis as it was felt that such comparisons would not be meaningful due to the small number of studies with such additions.

A further limitation is the focus on binge eating episode frequency as the only outcome measure to explore the effectiveness of DBT. Factors such as perceived self-efficacy to manage difficulties, regulate emotions and tolerate distress as well as perceived well-being are important in the context of clinical effectiveness, meaningful change and recovery. These factors may also help to explain the observable behaviour change in individuals with BN and BED (Lenz et al., 2013; Telch et al., 2000). Unfortunately, such outcomes were inconsistently reported in the selected primary studies and hence could not be analysed in the current meta-analysis. A focus on including such outcome measures and evaluating these in future reviews would be valuable.

Clinical Implications

Binge eating episodes can have a negative impact on physical and emotional well-being, fostering shame and guilt (Hepworth & Paxton, 2007). This meta-analysis provides preliminary evidence that DBT can lead to successful reductions in the frequency of such episodes. Further high-quality research exploring the efficacy of DBT in diverse samples and ways of involving families in DBT are needed before recommendations about its utility as a routine intervention for BN and BED can be formulated.

Conclusions

This meta-analysis provides promising results on the effectiveness of DBT to reduce binge eating episode frequency in individuals with sub- and full-threshold BN and BED. Findings from this meta-analysis are in line with previous meta-analyses that explored the effectiveness of mindfulness-based approaches including DBT in the context of problematic eating behaviours. Further, good quality research designs including control groups are needed to corroborate these findings, including further exploration of long-term effects of DBT on binge eating outcomes.

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EMPIRICAL STUDY

Children Overcoming Picky Eating (COPE) – A Cluster Randomised Control Trial

Abstract

Background: Food neophobia limits dietary variety in children and adults. Interventions to alleviate its impact on dietary variety have been developed for children with varying success. The potential effectiveness of mindfulness has received little attention. This trial aimed to explore the effectiveness of two mindfulness exercises on novel food acceptance.

Method: A cluster-randomised control trial with three trial arms compared the impact of two mindfulness exercises (mindful breathing and mindful raisin-eating) and a non-mindful control task on anticipated liking and intake of a novel fruit. Seventy-one children aged 10 to 12 years engaged in one of the three tasks at school over the course of five days and were offered a novel fruit at the end of the intervention period. Children self-reported mindfulness, food neophobia and anxiety at baseline and follow-up.

Results: Two mixed-effects models showed that controlling for effects of school and covariates (including mindfulness, food neophobia and anxiety), children in the mindful raisin-eating arm reported greater anticipated liking of a novel fruit and children in both mindfulness arms consumed greater amounts of a novel fruit than children in the control arm. Mixed-design ANOVAs indicated that mindfulness, food neophobia and anxiety did not change over time in each trial arm.

Discussion: The results provide promising evidence for the potential effectiveness of mindfulness to alleviate the impact of food neophobia on dietary variety in children. The mechanisms underlying its effectiveness remain unclear and further research, exploring long-term effects and the possibility to generalise these findings to other food groups such as vegetables, is needed.

Introduction

A balanced and varied diet is crucial for the optimal health and development of children and positively impacts on health outcomes of humans across the lifespan (World Health Organisation, 2003). The foundations for a healthy and varied diet are laid down in childhood. Reflecting this, research has indicated that the introduction of healthy foods into children's diets from an early age is crucial (Cashdan, 1994; Harris, 1993). Food preferences developed during infancy have been found to be stable and enduring, impacting on food choices in later childhood (Skinner, Carruth, Bounds, Ziegler, & Reidy, 2002). Research has also indicated that parents often find it difficult to introduce healthy foods, such as fruit and vegetables, into their children's diets successfully. A report by Public Health England (2014) has indicated that only 7% of girls and 10% of boys consume the recommended five or more portions of fruit and vegetables a day. Showing some improvement with age, 30% of adults and 41% of older adults (aged 65+) reportedly follow this guideline (Public Health England, 2014).

Food Neophobia – A Barrier to Dietary Variety

Food neophobia has been defined as the rejection of novel, unfamiliar foods prior to tasting (Dovey, Staples, Gibson, & Halford, 2008). It involves the rejection of novel foods on the basis of primarily visual properties such as colour and is associated with the same physiological responses as fear (Adessi, Galloway, Visalberghi, & Birch, 2005; Maratos & Staples, 2015; Raudenbusch & Capiola, 2012). Food neophobia has also been linked with increased anxiety and disgust reactions towards novel foods (Galloway, Lee, & Birch, 2003; Nordin, Broman, Garvill, & Nyroos, 2004; Raudenbusch & Capiola, 2012; Tuorila, Lähteenmäki, Pohjalainen, &

Lotti, 2001). It is thought that the physiological and emotional responses to novel foods influence their rejection (Brown & Harris, 2012a, 2012b).

Research has indicated that food neophobia varies with age, emerging gradually from weaning, reaching its peak when children are aged 2 to 6 years (Cashdan, 1994; Cooke, Wardle, & Gibson, 2003). From age 6 it gradually reduces, reaching more stable levels in adolescence (McFarlane & Pliner, 1997; Nicklaus, Boggio, Chabanet, & Issanchou, 2005; Pliner & Hobden, 1992). Effective interventions targeting food neophobia in children before they reach adolescence may hence be most beneficial for improving dietary variety in adolescence and adulthood. Evidence for gender differences in food neophobia is mixed, with some studies suggesting that males score more highly in food neophobia than females (Mascola, Bryson, & Agras, 2010; Tuorila et al., 2001), and others reporting no gender differences (Cooke, Carnell, & Wardle, 2006; Meiselman, King, & Gilette, 2010).

Food neophobia is present in all omnivorous species and is thought to be an evolutionary adaptive mechanism, limiting a child's risk of accidental poisoning at a time of increasing independence from caregivers (Pliner & Hobden, 1992; Pliner, Pelchat, & Grabski, 1993). In support of this view, research has indicated that the acceptance of certain food groups (fruit, vegetables and protein) is most affected by food neophobia (Cooke et al., 2006; Cooke et al., 2003). Research has also suggested that individuals with high levels of food neophobia might compensate for their limited intake of healthy foods by eating larger amounts of less healthy foods (MacNicol, Murray, & Austin, 2003; Siegrist, Hartmann, & Keller, 2013). Food neophobia hence negatively impacts on children's and adults' willingness to try new

foods, their food choices and limits their dietary variety (Jaeger, Rasmussen, & Prescott, 2017; Lafraire, Rioux, Giboreau, & Picard, 2016). This makes it difficult for individuals with high levels of neophobia to achieve a balanced diet consisting of recommended amounts of fruit and vegetables, proteins, fibres, mono- and polyunsaturated fats, minerals and vitamins; these are particularly important for the healthy development of children (Capiola & Raudenbusch, 2012; Falciglia, Couch, Gribble, Pabst, & Frank, 2000).

Food neophobia is related to picky/fussy eating, which is characterised by the rejection of familiar and novel foods prior to and after tasting, insufficient food intake and rejection of certain food textures, limiting dietary variety in children and adults (Falciglia et al., 2000). Research has shown that food neophobia and picky/fussy eating are positively correlated but predicted by different variables, indicating that they are conceptually distinct (Galloway et al., 2003). Picky/fussy eating appears to be predicted by environmental factors such as the availability and accessibility of foods in the (home) environment and parental feeding practices in infancy and later childhood (Blissett & Fogel, 2013; Galloway et al., 2003). Food neophobia on the other hand is an intrinsic factor that has genetic origins; Gemini studies have shown that food neophobia and preferences for fruit, vegetables and proteins have high heritability (Faith, Heo, Keller, & Pietrobelli, 2013; Fildes et al., 2014). Having said this, there are opportunities to positively impact on the expression of food neophobia through a variety of interventions, outlined below. In practice, the behavioural expressions of food neophobia and picky/fussy eating are difficult to distinguish; a number of studies and measures exploring barriers to food acceptance and variety in children and adults hence examine both concepts (Damsbo-Svendsen, Frøst, &

Olson, 2017; Lafraire et al., 2016; Mascola et al., 2010; Tharner et al., 2014). Together, food neophobia and picky/fussy eating are considered to be the most important “psychological barriers” to dietary variety in children (Dovey et al., 2008; Lafraire et al., 2016).

Overcoming Food Neophobia

A number of interventions such as sensory education (Mustonen & Tuorila, 2010), exposure (Nederkoorn, Theißen, Tummers, & Roefs, 2018) modelling (Hendy & Raudenbusch, 2000) and prompting (Blissett, Bennett, Fogel, Harris, & Higgs, 2016) have been used to target food neophobia. These approaches have all shown some effectiveness in improving children’s willingness to experience and tolerate sensory properties of new foods. Exposure to novel foods from an early age appears to be one of the most effective approaches by increasing familiarity and liking of novel foods (Dazeley & Houston-Price, 2015; Nederkoorn et al., 2018). In line with this, school-based approaches, involving repeated exposure, peer-modelling and rewards, have been used successfully to improve fruit and vegetable consumption, increase nutritional knowledge and to reduce the intake of unhealthy foods (Dudley, Cotton, & Peralta, 2015; Evans, Christian, Cleghorn, Greenwood, & Cade, 2012; Taylor, Upton, & Upton, 2015). The school environment and structure lends itself to the implementation of health interventions as it provides consistent and intensive contact with trusted carers and opportunities for peer-learning. Interventions that can be integrated into the school context are also cost-effective and positive outcomes can generalise to other settings such as the home environment (Lowe & Horne, 2009).

Mindfulness, Food Neophobia and Mechanisms of Behaviour Change

Mindfulness-based approaches have received limited attention, despite being potentially useful in moderating the impact of food neophobia on food acceptance and dietary variety in children. Mindfulness has been defined as moment-by-moment, non-judgmental, open awareness (Kabat-Zinn, 2005; Williams & Penman, 2011). Mindfulness has its origins in Eastern culture and is central to Buddhist traditions and meditation (Kabat-Zinn, 2003). It is increasingly being used in Western therapeutic approaches and has been found to be effective in improving outcomes in relation to a number of physical and mental health difficulties, improving emotion regulation, well-being and resilience (Emery, 2013; Roemer, Williston, & Rollins, 2015). Research has also begun to explore the potential benefits of mindfulness on obesity and weight loss (Olson & Emery, 2015) and problematic eating behaviours such as emotional eating, Bulimia Nervosa and Binge Eating Disorder (Godfrey, Gallo, & Afari, 2015; Katterman, Kleinman, Hood, Nackers, & Corsica, 2014). More recently, researchers have started to explore potential benefits of mindfulness interventions to increase the acceptance of novel and disliked foods in adults (Hong, Lishner, & Han, 2014; Hong, Lishner, Han, & Huss, 2011) and children (Hong, Hanson, Lishner, Kelso, & Steinert, 2018; Kennedy, Whiting, & Dixon, 2014).

Hong et al. (2011) explored the impact of a one-off mindful raisin-eating exercise on the anticipated liking of food and non-food items in a student population aged 18 to 41 years. Results showed that anticipated liking for both types of items increased following mindful raisin-eating but not non-mindful raisin eating. Hong et al. (2014) extended this research to explore whether mindfulness also impacted on actual intake in a student population. Participants engaged in a one-off mindful raisin-

eating exercise, a non-mindful raisin-eating exercise or a non-mindful listening exercise and were given access to foods afterwards. Results indicated that participants in the mindful raisin-eating group enjoyed the sampled foods more than those in the other groups. Nevertheless, those engaging in mindfulness did not sample a greater variety of foods. Recently, Hong et al. (2018) applied this research to 3-10-year-olds. Children in school settings were allocated to a mindfulness or exposure control condition and engaged in 16, 30-minute mindfulness sessions over 4 weeks. Following this period, children were offered a novel or disliked food over 4 consecutive days (a different food in each of the 4 weeks) and liking and intake were measured. The results indicated that children in the mindfulness condition sampled a wider variety and consumed greater amounts of the novel/disliked foods but groups did not differ in food liking. This suggests that mindfulness can have a positive impact on dietary variety, reducing the reluctance to try a new food but is not more effective than exposure in affecting liking. The repeated exposure to the target foods, peer-effects and modelling by a teacher are confounding factors; research has shown that in isolation, repeated exposure and modelling of intake by a trusted adult or peers, facilitate acceptance of unfamiliar foods in 3-7-year-olds (Hendy, 2002; Hendy & Raudenbusch, 2000; Wardle, Herrera, Cooke, & Gibson, 2003). Finally, Kennedy et al. (2014) explored the impact of Acceptance and Commitment Therapy-based mindfulness exercises with or without rewards, on the willingness of six 3-5-year-olds to approach and consume novel or disliked healthy foods at nursery. The results showed that mindfulness had a positive impact on tasting of fruit but not vegetables while improving children's willingness to approach both. Combining mindfulness with

tasting-contingent rewards led to larger increases in outcomes. The small sample size and lack of a control group limits the ability to draw strong conclusions, however.

The mechanism underlying the change in outcomes remains somewhat unclear. Shapiro, Carlson, Astin, and Freedman (2006) propose that mindfulness impacts on behaviour by improving emotion regulation, clarifying ones values, becoming more flexible in cognitive, emotional and behavioural domains and by increasing exposure. Accordingly, mindfulness is associated with a reduction in experiential avoidance, increasing the ability to tolerate experiences (emotions such as anxiety and physiological fear reactions) and to engage in behaviour that fits with values and goals (Papies, Pronk, Keesman, & Barsalou, 2015; Thompson & Waltz, 2010). Research by Papies et al. (2015) found that mindfulness could break links between thoughts/urges to eat palatable foods and action towards consuming these foods, supporting behaviour that fitted with healthy eating goals. Mindfulness is also linked with a reduction in physiological indices of anxiety and self-reported anxiety suggesting objective and subjective improvements in abilities to regulate negative emotions (Delgado et al., 2010; Kallapiran, Koo, Kirubakaran, & Hancock, 2015). Mindfulness may hence improve novel food acceptance by decreasing anxiety more generally, increasing children's awareness of their thoughts, feelings and physiological responses to a novel fruit, while also fostering the ability to accept and tolerate them and increasing curiosity about a novel food (Hong et al., 2018). Crucially, mindfulness increases exposure to thoughts, feelings and emotional reactions related to novel foods and mindful eating exercises also increase exposure to food and allow practicing mindfulness skills in this context specifically. The increase in exposure increases familiarity, which is known to affect novel food

acceptance (Nederkoorn et al., 2018). In fact, some of the existing exposure interventions are very similar to mindful eating exercises (e.g. Dazeley & Houston-Price, 2015). The combination of learning mindfulness skills and increasing exposure may hence underlie the observed effects.

Overall, research has indicated that neophobia and picky/fussy eating have negative and enduring effects on dietary variety and the consumption of healthy foods. A number of approaches to overcome these psychological barriers have been developed. Mindfulness is receiving increasing attention and has been shown to impact positively on intake of novel/disliked foods in children and adults. The exact mechanisms for this are not fully understood. Only few studies have begun to explore this and the validity of the findings is limited by small, homogenous samples with weak study designs. It is also unclear whether different mindfulness exercises lead to different outcomes. Nevertheless, the exploration of the impact of different mindfulness-based exercises on food neophobia could provide valuable insights into mechanisms and guide future interventions.

Aims and hypotheses

The trial aimed to explore the effectiveness of mindfulness exercises on two key outcome variables, namely novel food intake and anticipated food liking, in school children aged 10 to 12 years. Two specific hypotheses were tested in the main outcome analyses:

1. It was predicted that children who engaged in a food-related mindfulness exercise (over a five-day period) would express significantly higher levels of anticipated liking for a novel fruit when compared to children who engaged in a non-food related mindfulness exercise (over a five-day

period). In turn, children who engaged in a non-food related mindfulness exercise would show significantly higher levels of anticipated liking compared to children who engaged in a non-mindful control task.

2. It was predicted that children who engaged in a food-related mindfulness exercise (over a five-day period) would consume significantly greater amounts of a novel fruit when compared to children who engaged in a non-food related mindfulness exercise (over a five-day period). In turn, children who engaged in a non-food related mindfulness exercise would consume significantly greater amounts of a novel fruit when compared to children who engaged in a non-mindful control task.

The secondary aim of the study was to explore changes from baseline to follow-up in measured levels of mindfulness, food neophobia and anxiety. Two specific hypotheses were tested in the secondary analyses:

1. It was predicted that all children who engaged in mindfulness exercises (food and non-food related) would increase in levels of mindfulness and decrease in levels of anxiety from baseline to follow-up.

2. It was predicted that children who engaged in a food-related mindfulness exercise (over a five-day period) would show greater reductions in food neophobia when compared to children who engaged in a non-food related mindfulness exercise (over a five-day period). In turn, children who engaged in a non-food related mindfulness exercise would show greater reductions in food

neophobia when compared to children who engaged in a non-mindful control task.

Method

Design

A cluster-randomised control trial with three arms was conducted to evaluate the effectiveness of mindfulness on the main outcomes anticipated liking and novel fruit intake. Classrooms (clusters) were randomly allocated to one of three trial arms. Participants in arm one engaged in a non-mindful active comparison task (control arm), those in arm two engaged in a mindful breathing exercise, and those in arm three engaged in a mindful raisin-eating exercise.

Setting

Participants were recruited from two mainstream primary schools in and around Birmingham (UK) between November 2016 and December 2017 (see Appendix D for school invitations). Of 60 contacted schools, six registered an interest in taking part. Two schools were unable to participate due to time constraints, one did not have a sufficient amount of classrooms with 10-12-year-olds and one failed to recruit a sufficient number of children to the study (N<10). Participating schools received a £50 Amazon voucher as a thank-you for participation.

Participants

Overall, 71 children in nine classrooms aged 10-12 years, who were able to complete a number of self-report questionnaires in English, participated in this trial (see Table 1 for sample characteristics). Children with food allergies and those with close family members known to have food allergies were excluded from food testing. Overall, 300 parents were invited to consent to their child's participation; children also provided written consent (See Appendix E for parent and child information sheets

and consent forms). Participating children received stickers as a thank-you for participation; parents were debriefed (See Appendix F). Due to illness-related absences, two children completed the baseline but not the post-intervention measures, while one child completed the post-intervention but not baseline measures; 68 (95.77%) children engaged in five days of the intervention, while three children engaged in four days of the intervention.

Randomisation and Interventions

Classrooms were randomly allocated to one of three trial arms. Each trial arm was linked with a number (1=Control, 2=Mindful breathing, 3=Mindful raisin-eating) and a random sequence of numbers generated (https://www.randomizer.org). Each of the three classrooms was then assigned to one of the random numbers on the basis of their classroom teachers' last names in alphabetical order.

Control (Educational Colouring Book). Children in classrooms allocated to this trial arm completed a 10-page book containing food-facts, food-quiz questions and fruit/vegetable shapes to be coloured in. The book was handed out by teachers for five minutes on each of the five days; children completed two pages each day (see Appendix G).

Mindful Breathing. Children in classrooms allocated to this trial arm listened to an mp3 recording (male voice) of a guided mindful breathing exercise lasting 5 minutes. This exercise guides listeners to focus on the breath, sensations and movements associated with it. It explains how to approach thoughts in an open and non-judgemental way, while re-focusing on the breath.

Mindful Raisin-Eating. Children in classrooms allocated to this trial arm listened to an mp3 recording (male voice) of a guided mindful raisin-eating exercise

lasting 5 minutes. Raisins for each child, for each of the five days were given to the classroom teacher at the start of the week and children received one raisin to participate in the exercise each day. This exercise guides listeners to approach a raisin in a curious and open-minded way. It encourages the exploration of the raisin using all senses (sight, touch, smell, hearing, taste) sequentially, while guiding the listener to acknowledge thoughts and judgements and letting them go by re-focusing attention on the raisin.

Both mindfulness-exercises were played through the classroom's audio system ensuring the consistency of delivery and fidelity to the intervention. Both mindfulness exercises were retrieved from www.mindfulnessforteens.com and led by Dr. Dzung Vo, a paediatrician who has authored a book on mindfulness for young people and has developed a mindfulness training programme for young people that is based on Mindfulness-Based Stress Reduction and Cognitive Therapy programmes for adults.

Primary Outcome Measures

Anticipated Liking. The anticipated liking of a novel fruit, presented in a clear plastic container (5cm diameter), was explored using a 5-point hedonic liking scale ranging from 1 (*Disgusting*) to 5 (*Delicious*; see Appendix H). This scale was developed as part of a doctoral research programme and has been validated for children aged 10 to 12 years (Bennett, 2015).

Novel Fruit Intake. The novel fruit was weighed before and after children interacted with it. The amount consumed in grams was recorded and percentage consumed calculated to account for differences in density between novel fruits.

Percentage consumed will be referred to as *novel fruit intake* throughout the remainder of this paper.

Demographic and Screening Measures

Parents of all participating children completed a food allergy screening questionnaire, a brief demographic questionnaire, and reported which fruits their child had/had not previously eaten, as part of the consent procedure.

Demographic Information. Parents provided information on their own and their child's age (month and year of birth), gender, family ethnic background, total family annual income and highest educational attainment.

Screening and Novel Fruit Selection. Parents indicated whether their children or close relatives had known food allergies and what these were. Parents indicated whether their child had/had not eaten any of the suggested novel fruits used in this study (see Appendix I). These included dried apricots, fresh fig, Sharon fruit, dragon fruit, physalis or fresh/canned lychee. Twenty children were offered dried apricot, 22 were offered physalis and 20 were offered lychee. If children had not tried any or two of the suggested foods a novel fruit was randomly selected from the remaining choices. One child had previously tried all the suggested foods and was offered papaya based on parent recommendations. Six children were not offered a novel fruit due to conflicting information about the presence of food allergies in family members in the consent and screening forms.

Parents were invited to complete additional measures on child food neophobia and anxiety. These were posted to them directly and did not have to be completed. Only 14 completed questionnaires were returned and due to the low response rate

information on these measures and their relationships with child-report measures is presented in Appendix J only.

Secondary Measures

Children completed a range of self-report measures on the first and final day of the trial to explore baseline group differences and changes in factors at follow-up that might drive changes in primary outcome measures.

Mindfulness. Mindfulness was measured using the Child and Adolescent Mindfulness Measure (CAMM; Greco, Baer, & Smith, 2011). This 10-item measure explores mindfulness skills and has been validated for the measurement of the mindfulness trait in children aged 10 to 17 years. Items (e.g. I keep myself busy so I don't notice my thoughts or feelings.) are scored on a 5-point Likert scale ranging from 0 (*Never True*) to 4 (*Always True*) and summed, with higher scores indicating better mindfulness skills. The scale is reliable and has good internal consistency (Kuby, McLean, & Allen, 2015), with current Cronbach's alphas at baseline and follow-up reaching .69 and .84, respectively.

Food Neophobia. Food neophobia was measured using the Food Situations Questionnaire (FSQ; Loewen & Pliner, 2000). This 10-item measure allowed children to express how they would feel about eating a new food in 10 hypothetical scenarios. Items (e.g. If pudding at your friend's house was cannoli with chocolate sauce, how would you feel about eating that kind of pudding?) are scored on a 5-point Likert scale ranging from 1 (*Very Sad*) to 5 (*Very Happy*). Items are summed, ranging from 10 to 50 with higher scores indicating lower neophobia/greater willingness to try. The measure has been validated for use with children aged 7 to 12 years and has good

internal consistency (Damsbo-Svendsen et al., 2017), with current Cronbach's alphas at baseline and follow-up reaching .86 and .89, respectively.

Anxiety. Anxiety was measured using the Spence Children's Anxiety Scale (SCAS; Spence, 1998). The scale consists of 44 items (six filler items), measuring six aspects of anxiety (Separation Anxiety, Social Phobia, OCD, Panic/Agoraphobia, Physical Injury and GAD). Items (e.g. I would feel afraid of being on my own at home.) are measured on a 4-point Likert scale ranging from 0 (*Never*) to 3 (*Always*). A total score ranging from 0 to 114, with higher scores indicating greater anxiety symptoms, was calculated by adding the 38 anxiety items. The scale has been validated for use with children as young as 8 years. It has good internal consistency and acceptable test-retest reliability (Spence, 1998), with current Cronbach's alphas at baseline and follow-up reaching .9.

Hunger. Hunger was measured using the Teddy Picture Rating Scale (PRS; Bennett & Blissett, 2014). This scale consists of five bear silhouettes with varying amounts of food in their stomachs and accompanying vignettes describing hunger and satiety states ranging from 1 (*Very Hungry*) to 5 (*Very Full*). The Teddy PRS has been validated for use with children as young as 5 years and has been found to reflect hunger and satiety states reliably (Bennett & Blissett, 2014).

Procedure

The trial was conducted at school over the course of five days. Schools participated consecutively (School 1, 2, 1). On day one of the study, the researcher visited the school during the morning. Children in classrooms in each trial arm carried out a number of activities consecutively. The intervention and control task were led by classroom teachers independently over the next four days. The researcher

returned on day five to repeat questionnaire measures and offer children a novel fruit (see Figure 1 for details). The Ethical Review Committee of the University of Birmingham approved this study (**ERN_16-1234A**).

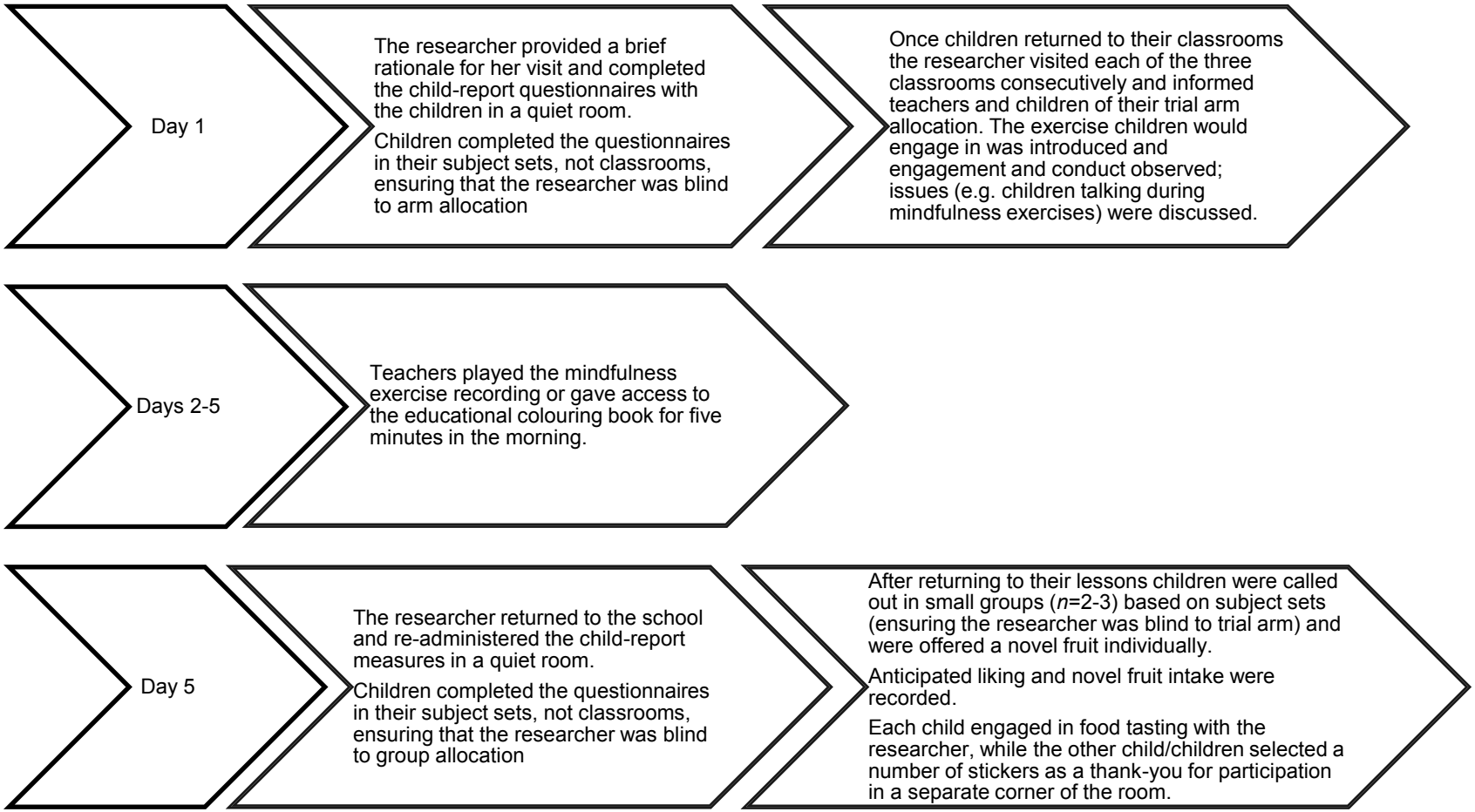

Figure 1. Overview and detailed description of the trial procedures

Data Analysis Plan

Visual inspection of the data indicated that the majority of variables were normally distributed. Parametric tests were therefore used throughout. For all analyses a *p*-value of .05 for statistical significance was used.

Preliminary analyses. Demographic characteristics and baseline differences in mindfulness, food neophobia and anxiety between trial arms were explored using one-way ANOVAs and χ^2 analyses for categorical data. The impact of covariates (age, annual household income, parent education, gender and ethnicity), on the primary outcome measures (anticipated liking and intake) and secondary measures (mindfulness, food neophobia, anxiety), was explored using Pearson's correlations and one-way ANOVAs. Furthermore, the impact of the type of novel fruit offered on the primary outcome measures was explored using one-way ANOVAs.

Analysis of primary outcome measures. Two linear mixed effects models (random intercepts models) were calculated to examine differences in anticipated liking and novel fruit intake by trial arm, while controlling for the effects of school context, baseline mindfulness, food neophobia and anxiety. All models were calculated step-by-step and fitted using robust estimation parameters (restricted maximum likelihood, REML) as these produce unbiased estimates of variance and covariance parameters while fitting linear mixed effects models (Bates, Mächler, Bolker, & Walker, 2015).

Initially, school was entered as a Random Effects Term (modelled by intercept). This acknowledged the hierarchical structure of the data and allowed modelling the random effect of school on anticipated liking and novel fruit intake (Model 1). Contextual variables, such as a child's school, introduce dependency in

the data, violating statistical assumptions for uncorrelated residuals. Explicitly modelling the impact of contextual variables helps to control for intra-class correlations to overcome the issues of non-independent observations (see Pinheiro, Bates, DebRoy, & Sarkar, 2006).

Secondly, fixed effects terms for baseline levels of mindfulness, food neophobia and anxiety were added to the model containing random effects for school to control for the effect of these covariates on anticipated liking and novel fruit intake. It was also explored whether controlling for them improved the model's goodness of fit (Model 2).

Finally, trial arm was added as an explanatory variable to evaluate whether trial arm significantly impacted on anticipated liking and novel fruit intake. It was also explored whether this improved the model's goodness of fit (Model 3). Post-hoc analyses (bonferroni correction) explored differences in liking and novel fruit intake between the three trial arms.

The goodness of fit of the three models was explored by comparing Schwarz's Bayesian Criterion (*BIC*), a chi-squared likelihood ratio test that corrects for number of parameters being estimated, as the models were calculated (Field, 2013). The *BIC* value is not interpretable in isolation but useful when comparing models and evaluating changes in goodness of fit as models are calculated. Smaller values indicate improved goodness of fit. To compare models, the *BIC* of the new model was subtracted from the *BIC* of the old model. A change in 10 points or more suggests a significantly improved fit (Raferty, 1995).

Exploratory analyses of secondary measures. To explore whether changes in mindfulness, food neophobia and anxiety from baseline to follow-up in the three trial

arms could explain differences in anticipated liking and intake between arms, a number of mixed-design ANOVAs were carried out. These analyses established whether there were changes in these variables over time and whether these changes differed by trial arm (interaction effects of trial arm and time).

Results

Preliminary Analyses

Demographic Characteristics. Table 1 shows the demographic characteristics of the children and caregivers who participated in this trial. The majority of forms were completed by parents (*n*=62), two were completed by other family members and two by children's legal guardians; in five cases demographic information was not provided by the child's caregiver; written consent was, however, given by a legal guardian.

Overall, three classrooms (23 children) were randomised to the Control arm, three classrooms (23 children) were randomised to the Mindful breathing arm and three classrooms (25 children) were randomised to the Mindful raisin-eating arm (see Appendix K for demographic characteristics by trial arm). One-way ANOVAs indicated that there was no significant difference in child age (F[2, 70]=.04, p=.96), annual household income (F[2, 56]=.93, p=.4), or parent education (F[2, 58]=1.8, p=.17) between trial arms. Chi-squared analyses indicated that trial arms did not differ in gender composition (χ^2[2, N=71]=.43, p=.81) or ethnicity (χ^2[10, N=66]=16.43, p=.09).

Baseline differences in secondary measures. One-way ANOVAs indicated that there were significant baseline differences in mindfulness and food neophobia between trial arms; children in the control arm were less mindful and more neophobic than children in the mindfulness arms; children in the mindfulness arms did not differ in mindfulness or neophobia. There were no baseline differences in anxiety between trial arms (Table 2).

Table 1

*Demographic characteristics of the sample overall (N=71)**

Variables	**Caregiver Characteristics**	**Child Characteristics**
Gender	50 females, 15 males	49 females, 22 males
Age, mean (*SD*)	39.57 (7.46)	10.36 (.51)
Age range (years)	25 – 61	10 – 12
Educational level	6.6% Qualified professional (*n*=4)	
	19.7% University graduate (*n*=12)	
	18% AS/A-Levels (*n*=11)	
	31.1% O-Levels, CSEs or GCSEs (*n*=19)	
	9.8% Some secondary education (*n*=6)	
	8.2% Other (*n*=5)	
	6.6% No formal qualifications (*n*=4)	
Annual household income	6.8% > £75000 (*n*=4)	
	1.7% £60-75000 (*n*=1)	
	3.4% £45-60000 (*n*=2)	
	23.7% £30-45000 (*n*=14)	
	27.1% £15-30000 (*n*=16)	
	37.3% < £15000 (*n*=22)	
Ethnicity	50% Asian/Asian British (*n*=33)	
	33.3% White British (*n*=22)	
	9.1% Other (*n*=6)	
	4.5% Mixed (*n*=3)	
	3% Black British (*n*=2)	

* Note: five parent respondents failed to provide information on their ethnicity, six on gender, eight on age, and ten on education

Table 2

Overview of baseline scores and differences in secondary measures between trial arms

Secondary Measures	**Control arm**	**Mindful breathing arm**	**Mindful raisin-eating arm**	**One-way ANOVA**
Mindfulness (CAMM)	*N*=19	*N*=17	*N*=21	*F*(2, 61)=11.34, *p*<.001
	M=18.74	*M*=26.24	*M*=25.57	
	SD=4.74	*SD*=4.76	*SD*=6.98	
Food Neophobia (FSQ)	*N*=19	*N*=20	*N*=22	*F*(2, 63)=13.45, *p*<.001
	M=25.95	*M*=31	*M*=34.77	
	SD=6.54	*SD*=5.28	*SD*=6.8	
Anxiety (SCAS)	*N*=14	*N*=14	*N*=17	*F*(2, 49)=2.38, *p*=.1
	M=39.79	*M*=37.07	*M*=35.38	
	SD=15.34	*SD*=14.74	*SD*=17.15	

Note. Differences in *N*-values are due to absences and missed responses on individual questionnaire measures.

Covariates

Pearson's correlations and one-way ANOVAs were carried out to explore whether the main outcome measures anticipated liking and novel fruit intake and secondary measures (mindfulness, food neophobia, anxiety), were associated with potential confounds such as child age, gender, ethnicity, parent education or annual household income in the sample as a whole (Table 3).

None of the potential confounds were associated with anticipated liking or novel fruit intake. One-way ANOVAs indicated that the type of novel fruit offered (Apricot, Lychee, Physalis, Papaya) did not impact on anticipated liking (F[2, 43]=2.15, p=.13) or novel fruit intake (F[3, 62]=1.81, p=.16).

Pearson's correlations indicated mindfulness was not associated with any of the potential confounds and no gender differences were observed. Baseline and follow-up food neophobia were positively associated with child age, indicating that older children were less neophobic. No gender differences were observed. Baseline and follow-up anxiety were negatively associated with annual household income, indicating that children whose caregivers reported having a larger income were less anxious. Chi-squared analyses showed that girls self-reported higher anxiety levels than boys at baseline and follow-up.

Table 3

Relationships between primary outcome measures and secondary measures and potential confounding variables, as well as differences in these variables by gender and ethnicity

	Anticipated Liking	**Novel Fruit Intake**	**CAMM baseline**	**CAMM follow-up**	**FSQ baseline**	**FSQ follow-up**	**SCAS baseline**	**SCAS follow-up**
Age	-.02	-.04	-.03	.02	.28*	.28*	-.02	-.02
Income	.23	.16	.15	.08	.04	-.05	-.32*	-.34*
Education	-.03	-.13	.04	.08	.06	.1	-.22	-.15
Gender	$F(1, 43)=2.59$, $p=.12$	$F(1, 62)=.37$, $p=.55$	$F(1, 63)=.31$, $p=.58$	$F(1, 63)=2.85$, $p=.1$	$F(1, 66)=.23$, $p=.63$	$F(1, 64)=.41$, $p=.52$	$F(1, 62)=9.78$, $p=.003$	$F(1, 60)=9.77$, $p=.003$
Ethnicity	$F(3, 38)=.42$, $p=.74$	$F(4, 57)=1.68$, $p=.17$	$F(4, 59)=1.36$, $p=.26$	$F(4, 58)=1.38$, $p=.25$	$F(4, 62)=2.26$, $p=.07$	$F(4, 60)=1.45$, $p=.23$	$F(4, 59)=1.85$, $p=.13$	$F(4, 56)=.39$, $p=.82$

* $p<.05$

Analysis of Primary Outcome Measures

Descriptive statistics for anticipated liking and intake can be seen in Table 4. Larger values indicate greater anticipated liking and novel fruit intake.

Table 4

Descriptive statistics for the primary outcome measures Anticipated Liking and Novel Fruit Intake for each of the three trial arms at follow-up

Outcome	**Control arm**	**Mindful breathing arm**	**Mindful raisin-eating arm**
Anticipated	*N*=17	*N*=20	*N*=23
Liking	*M*=2.59	*M*=2.48	*M*=3.09
	SD=.8	*SD*=.94	*SD*=.93
Novel Fruit	*N*=20	*N*=20	*N*=23
Intake	*M*=18.48	*M*=51.32	*M*=51.47
	SD=29.58	*SD*=45.76	*SD*=48

Anticipated Liking. To examine differences in anticipated liking of a novel fruit, a mixed effects model was calculated. School was entered as a contextual variable acknowledging the hierarchical nature of the data and potential random effects of school on the data (Model 1, intercept model). A significant random effect for school was observed $F(1, 59)=519.25$, $p<.001$, $BIC=171.37$.

Secondly, fixed effects for baseline mindfulness, food neophobia and anxiety were added to the model (Model 2). This significantly improved the model's goodness of fit; $BIC=149.68$ (BIC_{old}-$BIC_{New}=21.69$).

Finally, the fixed effects term for trial arm was added to the model; this significantly improved the model's goodness of fit; $BIC=137.63$ (BIC_{old} - $BIC_{New}=12.05$). Fixed effects terms for trial arm $F(2, 40.55)=7.59$, $p=.002$, mindfulness $F(1, 40.66)=9.9$, $p=.003$ and anxiety $F(1, 40.05)=4.78$, $p=.04$ were significant, while the term for food neophobia was not $F(1, 40.4)=.51$ $p=.48$.

Overall, the results indicate that controlling for school effects, baseline levels of mindfulness and anxiety, anticipated liking significantly differed between trial arms at follow-up. Post-hoc analyses indicated that children in the Control arm gave lower anticipated liking ratings than children in the Mindful raisin-eating arm (-.96, $p=.03$) but not the Mindful breathing arm (.11, $p=.1$). Children in the mindfulness arms significantly differed in anticipated liking; children in the Mindful raisin-eating arm gave higher anticipated liking ratings than children in the Mindful breathing arm (1.07, $p=.002$; Figure 2).

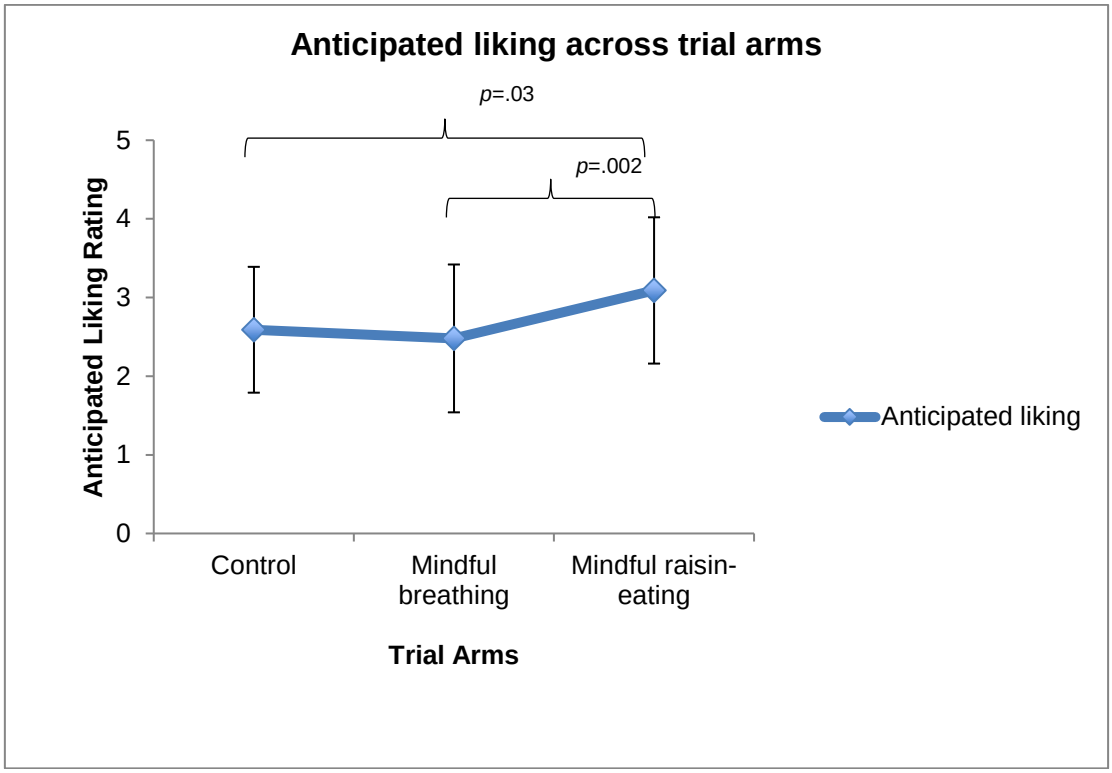

Figure 2. Anticipated liking ratings by trial arm and rating differences between arms at follow-up

Intake. To examine differences in novel fruit intake, a mixed effects model was calculated. School was entered as a contextual variable, acknowledging the hierarchical nature of the data and potential random effects of school (Model 1, intercept model). A significant random effect for school was observed $F(1, 62)=53.72$, $p<.001$, $BIC=658.55$.

Secondly, fixed effects for baseline mindfulness, food neophobia and anxiety were added to the model (Model 2). This significantly improved the model's goodness of fit; $BIC=513.07$ (BIC_{old}-$BIC_{New}=145.48$).

Finally, the fixed effects term for trial arm (explanatory variable) was added to the model. This significantly improved the model's goodness of fit; $BIC=490.74$ (BIC_{old} - $BIC_{New}=22.33$). Fixed effects terms for trial arm $F(2, 43.69)=4.08$, $p=.02$ and mindfulness $F(1, 43.45)=7.16$, $p=.01$ were significant, while terms for food neophobia $F(1, 43.06)=.11$ $p=.74$ and anxiety $F(1, 43.2)=1.58$, $p=.22$ were not.

Overall, the results indicate that controlling for school effects and baseline levels of mindfulness, children in the three trial arms significantly differ in novel fruit intake at follow-up. Post-hoc analyses indicated that children in the Control arm consumed significantly less of a novel fruit than children in the Mindful breathing arm (-42.91, $p=.04$) and the Mindful raisin-eating arm (-46.22, $p=.04$). Children in the two mindfulness arms did not significantly differ in novel fruit intake (3.31, $p=1$; Figure 3).

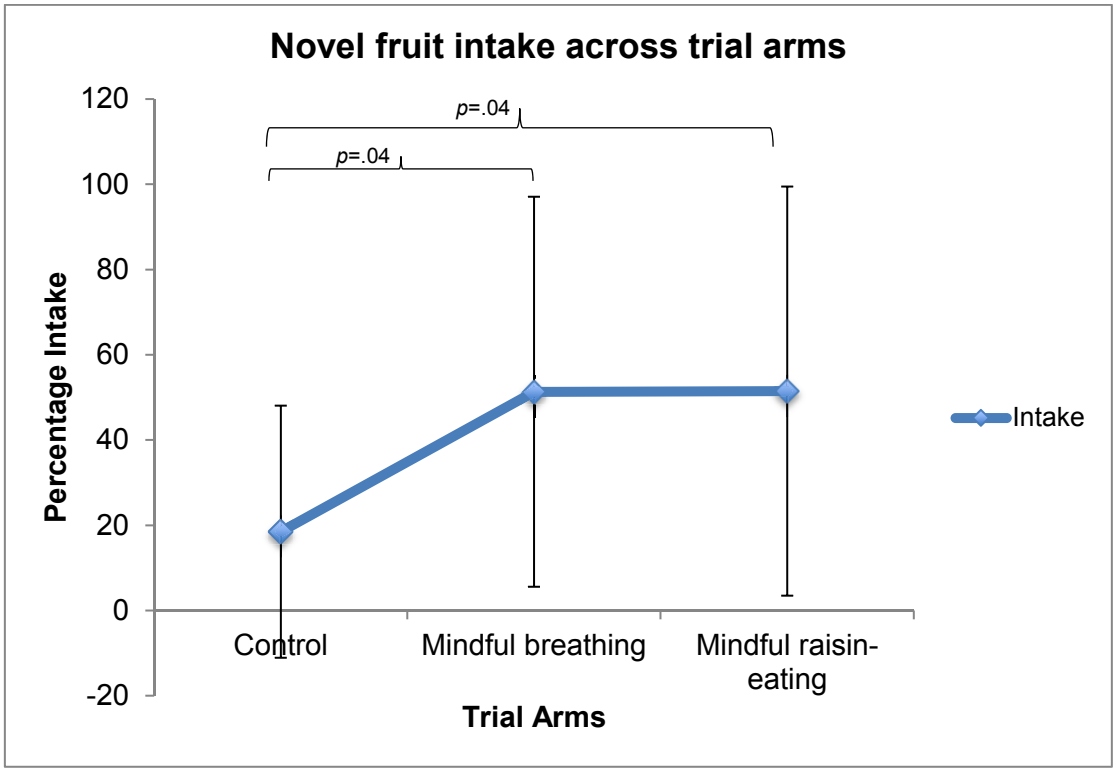

Figure 3. Percentage of novel fruit intake by trial arm and intake differences between arms follow-up

Exploratory analyses of secondary measures.

Exploratory analyses were conducted to explore factors that were predicted to be related to potential mechanisms of change in primary outcome measures. Changes in mindfulness, food neophobia and anxiety, from baseline to follow-up points in the three trial arms, were explored in line with predicted hypotheses, using mixed-design ANOVAs.

Mindfulness. Descriptive statistics for mindfulness measured by the CAMM can be seen in Table 5. Higher scores reflect greater mindfulness. Mindfulness scores were in line with scores reported in previous studies looking at mindfulness in non-clinical populations of children aged 10 to 17 years (Greco et al., 2011).

Table 5

Descriptive statistics for mindfulness measured by the CAMM in each trial arm at baseline and follow-up time points

Mindfulness	**Control arm**	**Mindful breathing arm**	**Mindful raisin-eating arm**
CAMM baseline	*N*=19 *M*=18.74 *SD*=4.74	*N*=17 *M*=26.24 *SD*=4.76	*N*=21 *M*=25.57 *SD*=6.98
CAMM follow-up	*N*=19 *M*=22.32 *SD*=7.62	*N*=17 *M*=27.82 *SD*=5.5	*N*=21 *M*=27.14 *SD*=8.56

The analyses indicated that there was a significant main effect for time point $F(1, 54)=7.58$, $p=.01$, indicating that mindfulness scores increased from baseline to follow-up (mean increase=2.25). Post-hoc analyses indicated that there was no significant change in mindfulness scores from baseline to follow-up in the Control arm $t(18)=-1.96$, $p=.07$, the Mindful breathing arm $t(16)=-1.15$, $p=.27$ or the Mindful raisin-eating arm $t(20)=-1.67$, $p=.11$. This may be due to the small sample sizes in each trial arm and a lack of power to detect changes. There was a significant main effect for trial arm $F(1, 54)=6.98$, $p=.002$. Children in the Control arm had significantly lower mindfulness scores than children in the Mindful breathing (-6.5, $p=.005$) or Mindful raisin-eating (-5.83, $p=.008$) arms. Children in the two mindfulness arms did not differ in mindfulness scores (.67, $p=1$). ANOVAs exploring differences in follow-up mindfulness, controlling for baseline differences, indicated that trial arms did not differ $F(2, 53)=.02$, $p=.98$. Finally, time point and trial arm did not interact $F(2, 54)=.67$, $p=.52$ (Figure 4).

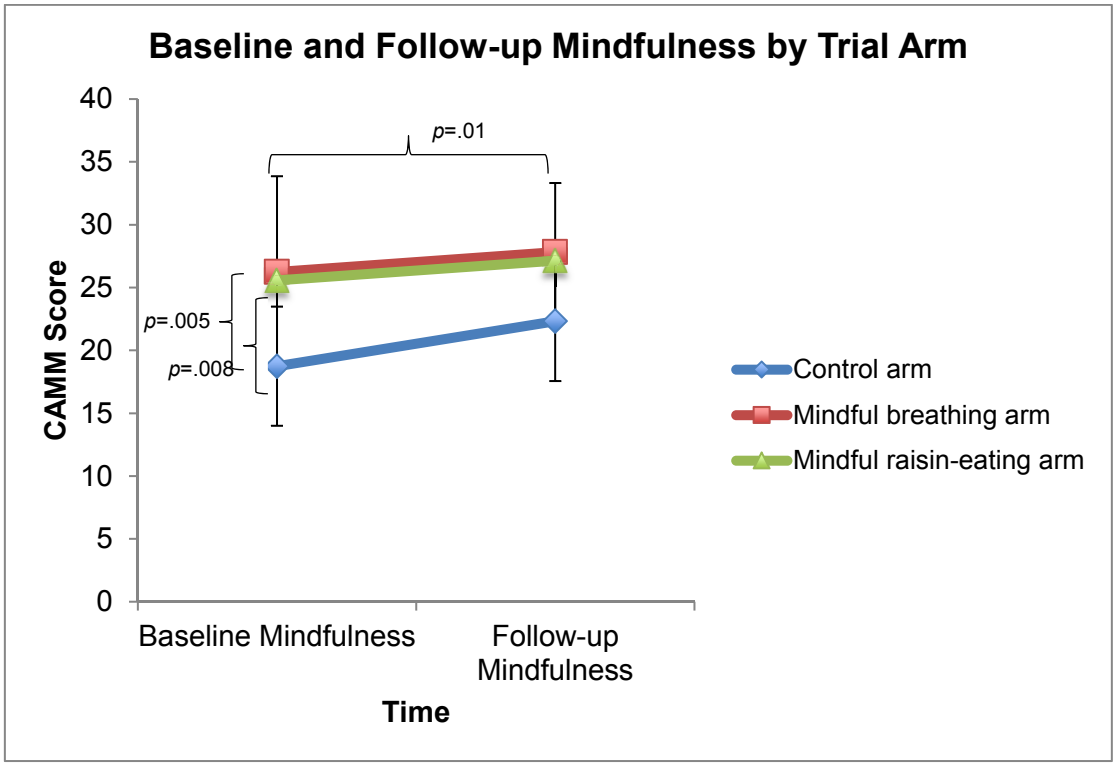

Figure 4. Mindfulness scores measured by the CAMM in each trial arm at baseline and follow-up

Food Neophobia. Descriptive statistics for neophobia measured by the FSQ can be seen in Table 6. Higher scores indicate lower neophobia and greater willingness to try unfamiliar foods. Food neophobia scores were representative of scores reported in previous studies looking at food neophobia in non-clinical populations of children aged 10 to 12 years (Loewen & Pliner, 2000).

Table 6

Descriptive statistics for food neophobia measured by the FSQ in each trial arm at baseline and follow-up

Food Neophobia	**Control arm**	**Mindful breathing arm**	**Mindful raisin-eating arm**
Baseline FSQ	*N*=19	*N*=20	*N*=22
	M=25.95	*M*=31	*M*=34.77
	SD=6.54	*SD*=5.28	*SD*=6.8
Follow-up FSQ	*N*=19	*N*=20	*N*=22
	M=26.89	*M*=30.9	*M*=34.23
	SD=6.34	*SD*=5.19	*SD*=9.31

The analyses indicated that there was no significant main effect for time $F(1, 57)=.45$, $p=.5$; neophobia; scores did not significantly change from baseline to follow-up. There was a significant main effect for trial arm $F(2, 57)=10$, $p<.001$. Children in the Control arm had significantly lower neophobia scores than children in the Mindful breathing arm (-4.9, $p=.03$) and the Mindful raisin-eating arm (-8.11, $p<.001$). Children in the two mindfulness arms did not significantly differ in neophobia scores (3.21, $p=.24$). ANCOVAs (controlling for child age) exploring differences in follow-up neophobia, while controlling for baseline differences, indicated that trial arms did not

differ $F(2, 56)=.03$, $p=.97$. Finally, time point and trial arm did not interact $F(2, 57)=.5$, $p=.61$ (Figure 5).

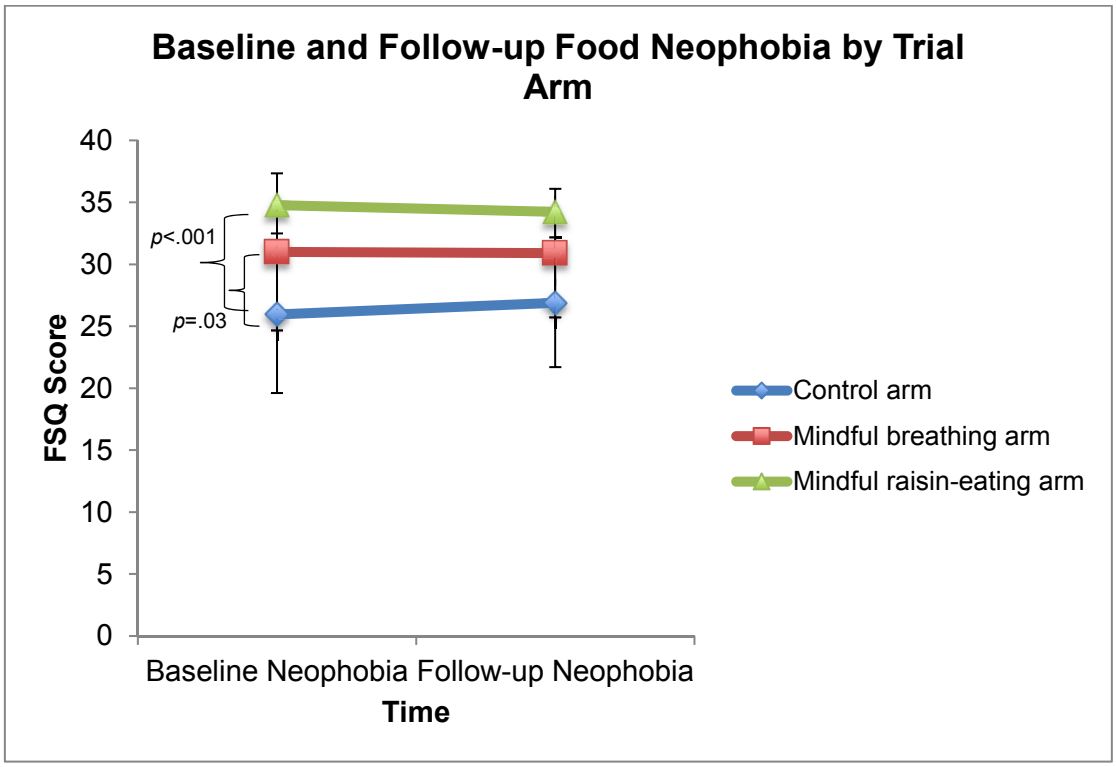

Figure 5. Food Neophobia scores measured by the FSQ in each trial arm at baseline and follow-up (controlling for child age)

Anxiety. Descriptive statistics for anxiety measured by the SCAS can be seen in Table 7. Higher scores indicate the presence of greater symptoms of anxiety. Anxiety scores in the current sample were in line with scores reported in previous studies looking at anxiety levels in non-clinical populations of children aged 8 to 12 years (Spence, 1998).

Table 7

Descriptive statistics for anxiety measured by the SCAS in each trial arm at baseline and follow-up

Anxiety	**Control arm**	**Mindful breathing arm**	**Mindful raisin-eating arm**
Baseline SCAS	*N*=14	*N*=14	*N*=17
	M=39.79	*M*=37.07	*M*=35.38
	SD=15.34	*SD*=14.74	*SD*=17.15
Follow-up SCAS	*N*=14	*N*=14	*N*=17
	M=32.57	*M*=34.21	*M*=32.59
	SD=14.38	*SD*=14.96	*SD*=20.03

The analyses indicated that there was no significant main effect for time *F(1, 41)=1.98, p*=.17*,* or trial arm *F*(2, 41)=.12, *p*=.89 and no significant interaction between time point and trial arm *F*(2, 41)=1.77, *p*=.18 (Figure 6).

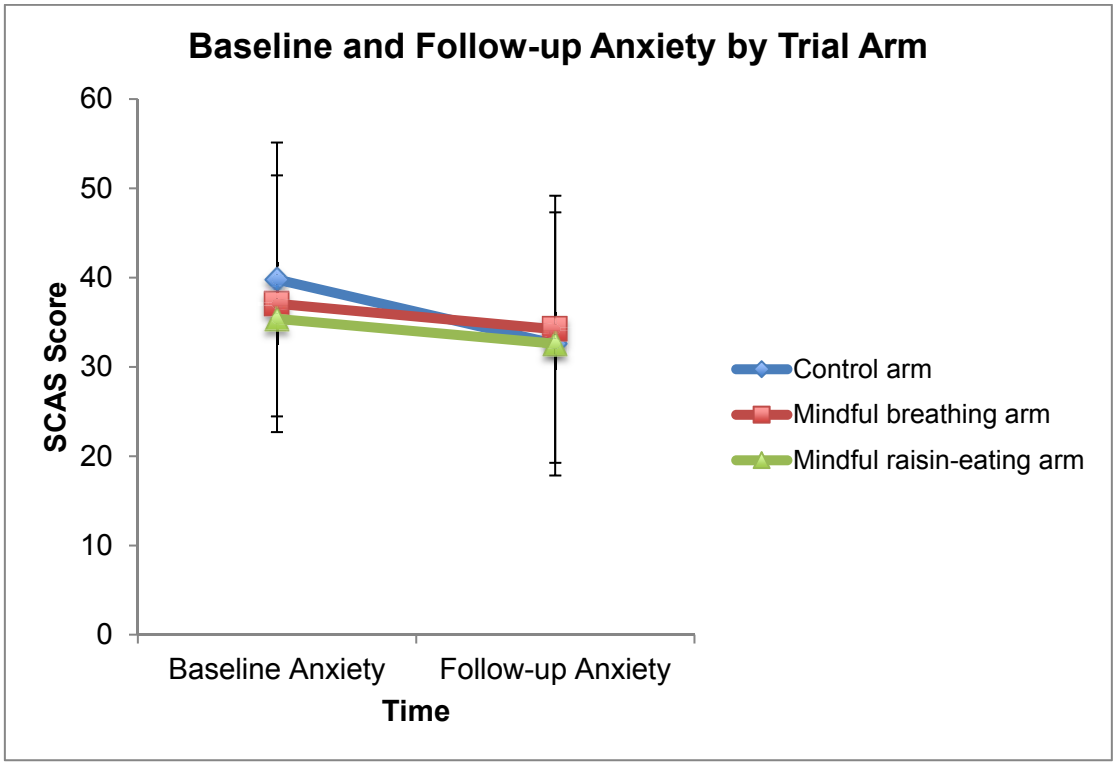

Figure 6. Anxiety scores measured by the SCAS in each trial arm at baseline and follow-up (controlling for family annual income)

Discussion

This trial explored the impact of mindfulness-based exercises on anticipated liking and novel fruit intake in 10-12-year-olds.

Summary of the Findings

Two key hypotheses were addressed. Firstly, it was hypothesised that children who engaged in a food-related mindfulness exercise (Mindful raisin-eating arm) would express significantly higher levels of anticipated liking for a novel fruit when compared to children who engaged in a non-food related mindfulness exercise (Mindful breathing arm), who in turn would show significantly higher levels of anticipated liking when compared to children who engaged in a non-mindful control task (Control arm). This hypothesis was partly supported. Children in the Mindful raisin-eating arm expressed greater anticipated liking for a novel fruit than children in the Mindful breathing arm of the trial. Contrary to the hypothesis, however, children in the Mindful breathing arm and the Control arm did not differ in anticipated liking.

Secondly, it was hypothesised that children who engaged in a food-related mindfulness exercise (Mindful raisin-eating arm) would consume significantly greater amounts of a novel fruit when compared to children who engaged in a non-food related mindfulness exercise (Mindful breathing arm), who in turn would consume significantly greater amounts of a novel fruit when compared to children who engaged in a non-mindful control task (Control arm). This hypothesis was partly supported. Although children in the Mindful raisin-eating and Mindful breathing arms did not differ in novel fruit intake, they did consume a greater amount of the novel fruit than children in the Control arm.

Findings in Relation to Previous Work

The results suggest that anticipated liking is improved by a food-related mindfulness exercise only. This finding could be explained by the exposure effect, which has been shown to positively impact on food neophobia (Mustonen, Oerlemans, & Tuorila, 2012; Nederkoorn et al., 2018). Exposing children to a raisin and encouraging them to focus on its sensory properties curiously and non-judgementally may have fostered skills that generalised to the novel fruit, leading to a more favourable appraisal of its (anticipated) sensory properties. The lack of such an effect in the Mindful breathing arm supports this conclusion, suggesting that the exposure to a fruit in the mindfulness exercise and learning mindfulness skills in this context were key aspects for increasing anticipated liking of a novel fruit (Mustonen et al., 2012; Nederkoorn et al., 2018).

The results also suggest that brief mindfulness exercises, whether food-related or not, can improve actual novel fruit intake. The change in observable behaviour in the absence of consistent changes in anticipated liking is in line with research, showing that behavioural change and changes in subjective evaluation are independent processes and that changes in subjective attitudes may follow overt behaviour change (Festinger, 1957; Priester, Cacioppo, & Petty, 1996; Smith & Mackie, 2007; Wells & Petty, 1980). The present findings are also in keeping with results by Hong et al. (2018) who observed improved intake but not liking of novel or disliked foods in 3-10-year-olds following a mindfulness intervention. Children in both mindfulness arms engaged in exercises fostering openness, curiosity and non-judgemental awareness of the present moment and experiences (Kabat-Zinn, 2005; Williams & Penman, 2011). Application of these skills in the context of tasting a novel

fruit could have meant that children were more aware of their thoughts and judgements and physiological reactions associated with disgust and anxiety, while being able to tolerate these and engage in behaviour that was not driven by these reactions (Brown & Harris, 2012a, 2012b; Galloway et al., 2003; Nordin et al., 2004; Tuorila et al., 2001). This in turn may have facilitated behaviour towards the novel fruit, increasing novel fruit intake in the Mindfulness arms compared to the Control arm. Changes in anticipated liking may follow this approach behaviour in both trial arms (Dazeley & Houston-Price, 2015; Priester et al., 1996).

Exploring Possible Mechanisms for Changes in Anticipated Liking and Novel Fruit Intake

The secondary aim of this study was to explore changes in mindfulness, food neophobia and anxiety from baseline to follow-up in each of the trial arms to allow an exploration of potential mechanisms that may contribute to the observed differences in primary outcomes. It was hypothesised that children in the Mindfulness arms would be more mindful, less neophobic and less anxious than children in the Control arm at follow-up. These hypotheses were not confirmed.

Although children became more mindful overall, there were no increases in mindfulness in individual trial arms suggesting that the mindfulness intervention did not lead to changes detectable by the Child and Adolescent Mindfulness Measure (CAMM). These results are similar to those reported by other researchers and a review into changes in mindfulness following mindfulness interventions (Huppert & Johnson, 2010; Visted, Vøllestad, Birkeland Nielsen, & Nielsen, 2015) and they raise the question of what underlies the observed differences in novel fruit intake and anticipated liking. Although the CAMM did not indicate an increase in mindfulness for

children in the Mindfulness arms it is possible that the measure was not sensitive or specific enough to detect such changes. The CAMM conceptualises mindfulness as a trait, suggesting that individuals can act more or less mindfully independent of situations. Greco et al. (2011) note that the CAMM may be more likely to measure internal mindfulness skills rather than observable skills, as child self-reports and teacher ratings are only moderately related. It is likely that a longer and/or more intensive intervention would have been necessary for children to internalise the learnt mindfulness skills, become aware of associated changes in their behaviour and report these using the CAMM (Kuby et al., 2015). In line with this, Vickery and Dorjee (2016) also failed to observe changes in mindfulness measured by the CAMM following a 6-module mindfulness intervention with 7-9-year-olds. Nevertheless, mindfulness increased from post intervention to three-month follow-up as children continued to engage in brief informal mindfulness practice with their teachers. Huppert and Johnson (2010) observed that practice of mindfulness exercises was a key factor moderating changes in mindfulness and well-being from baseline to follow-up in adolescent boys enrolled in a mindfulness programme, consisting of four weekly 40-minute mindfulness sessions, delivered by teachers.

There was no detectable reduction in food neophobia or anxiety over the course of the intervention period. Neophobia is a complex and multifaceted concept and different measures of neophobia may capture different aspects of neophobia (Damsbo-Svendsen, 2017). The Food Situations Questionnaire (FSQ) explored children's willingness to try foods in different situations (Loewen & Pliner, 2000). It is possible, however, that the mindfulness exercises impacted on non-situational aspects of the novel fruit, such as sensory properties, fostering skills that allowed

children to accept negative evaluations of and disgust reactions towards the novel fruit without needing to act on these (e.g. noticing the thought “that fruit smells weird” and an urge to reject it but approaching it regardless of these thoughts and urges). Finally, the lack of evident changes in anxiety may also be associated with the brief duration of the mindfulness intervention or the sensitivity and specificity of the Spence Children’s Anxiety Scale.

Limitations and Further Research

Sample size and composition. The number of children in each of the three arms was small, and the need to randomise clusters rather than individual children may have limited the power to detect changes in outcomes. Additionally, there was a slight bias towards girls participating in this trial. While this partly reflects gender differences in schools, this may have been exacerbated by parental perceptions of their child’s ability to benefit from the intervention, with parents of boys perhaps feeling less optimistic about possible changes. A replication of the current results with larger, gender-balanced samples is hence required. Finally, 10-12-year olds were recruited for this trial as research suggests that there is still variability in food neophobia levels at this age before it stabilizes from age 13 to adulthood (Nicklaus et al., 2005). This may hence be the age group where interventions leading to changes in dietary variety can have a significant impact on dietary variety in adolescence and adulthood. Furthermore, 10-12-year-olds were thought to have the cognitive abilities necessary to complete measures on mindfulness and the maturity necessary to engage in group-based mindfulness-exercises (Greco et al., 2011; Kennedy et al., 2014).

Type, duration and delivery of Mindfulness interventions. Audio-recorded mindful breathing and raisin-eating exercises were used to ensure fidelity and consistency in their presentation and delivery. Nevertheless, more interactive mindfulness exercises that involve "participation" rather than mindful breathing may have led to better engagement and outcomes (Kennedy et al., 2014). Although most children accepted the raisin used in the raisin-eating exercise, using a food that was well liked by all children e.g. chocolate, may have led to better engagement and outcomes. As discussed above, the mindfulness interventions were brief and the trial only lasted five days. More intensive exercises presented over a longer period of time may have led to more changes in primary outcomes and secondary measures. Furthermore, integrating the mindfulness exercises into the wider curriculum as demonstrated in the *'Paws b'* and *'.b'* mindfulness programmes may have been more powerful, supporting generalised changes in child wellbeing and behaviour (Mindfulness in Schools, 2017, 5 June). Considering the results of the current study, further exploration of the impact of more integrated mindfulness-based approaches, different exercises and intervention durations/intensities on eating behaviour could be warranted.

Outcome measurement. Unfortunately, anticipated liking and novel fruit intake were measured at follow-up but not at baseline, limiting our certainty to some degree that the mindfulness exercises per se led to a change in novel fruit intake by trial arm. Analyses of differences in primary outcomes allowed controlling for baseline levels of mindfulness, neophobia and anxiety to address this. As baseline exposure to a novel fruit might have primed children to the main outcome measure, this was not included. Future research could consider alternative outcome measures such as changes in

heart rate and cortisol levels to clarify whether changes in physiological reactivity to novel foods help to explain the observed effects (Feldman, Lavallee, Gildawie, & Greeson, 2016).

Control task. Children in the Control arm read food-facts, answered food-quiz questions and coloured in fruit/vegetable shapes for five minutes each day. Although this task was meant to represent a non-mindful control task, colouring activities like these may well represent mindful activities, while also exposing children to fruits and vegetables. This may also explain the small increase in mindfulness from baseline to follow-up reported by children in this trial arm. The effects of the selected mindfulness exercises on outcomes may hence have been weakened as a consequence. While children in the mindfulness arms were guided through the mindfulness exercises by an audio recording, encouraging silent engagement with and focus on physical sensations, feelings and shifting of attention away from thoughts and judgements, there was no such guidance for children in the Control arm. Children in the Control arm engaged in conversation throughout the task, discussing quiz questions, colours to use and general issues around day-to-day school and home life. The qualitative experience of the control task hence appears to be different from the experience of the mindfulness exercises.

Baseline differences. Despite the cluster-randomisation process, children in the Control arm were less mindful and more anxious than children in the Mindfulness arms. The researcher was blind to the trial arm children were allocated to and children completed the questionnaires and engaged in the food testing session individually and independently of the trial arm, suggesting that neither biases in the collection of outcome data, nor the influence of peer factors can explain these

differences. Further exploration of the data suggested that gender, age and cohort effects did not explain these differences, suggesting that they reflect random differences.

Clinical Implications

Food neophobia limits dietary variety in children and adults. Alleviating some of the restrictive effects of food neophobia before stable food preferences have developed is hence an important area of research. Mindfulness interventions are showing promising results, improving intake of novel and disliked foods in 3-10-year-olds. The current trial adds to these findings, providing further evidence that in 10-12-year-olds, food and non-food related mindfulness exercises can increase novel fruit intake, while only a food-related mindfulness exercise increased anticipated liking. While the exact mechanisms underlying these changes in observed behaviour remain unclear, exposure effects as well as fostering mindfulness skills such as non-judgemental awareness and curiosity may play a role; further exploration of the mechanisms is required.

The finding that favourable outcomes for intake can be seen without the need to engage children in a mindful eating task may be particularly useful in circumstances where children are unwilling to consume any foods offered for this task. Additionally, being able to use mindfulness exercises to increase dietary variety outside of a mealtime context may help to reduce stress associated with mealtimes for children and their caregivers. Mindfulness is a cost- and time-effective intervention that can be delivered across multiple contexts. Many schools are currently using mindfulness to foster resilience, reduce stress and improve mental

health in their pupils; a positive impact on pupils' willingness to try new and previously disliked foods may be a by-product that is overlooked and could perhaps be emphasised more readily. Especially the caregivers of pupils who are known to struggle with the consumption of fruits and vegetables could be encouraged to offer new or disliked foods to their children while encouraging them to apply mindfulness skills to tasting these foods. Further research exploring the necessary intensity and duration of interventions to improve novel food intake in children of different age-groups will be helpful to guide those interested in using this approach.

Conclusions

This cluster-randomised control trial adds to the existing literature examining the effect of mindfulness interventions on improving intake of novel or disliked foods by including an active comparison control group and controlling for peer and school effects on outcomes. Additionally, this study has begun to explore factors that may explain changes in novel fruit intake and liking. Overall, the results suggest that despite the fact that engagement in mindfulness exercises does not lead to detectable changes in self-reported mindfulness, neophobia or anxiety, the mindfulness exercises are linked with greater anticipated liking (mindful raisin-eating only) and greater novel fruit intake (mindful breathing and raisin-eating), making this a promising, cost- and time-effective intervention to improve the variety and amount of fruit children consume. Further research exploring long-term effects and the possibility to generalise these findings to other food groups such as vegetables is needed.

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EXECUTIVE SUMMARY: PUBLIC DOMAIN BRIEFING DOCUMENT

The effectiveness of Dialectical Behaviour Therapy for binge eating behaviour in Bulimia Nervosa and Binge Eating Disorder: A Meta-Analysis

Background

Bulimia Nervosa and Binge Eating Disorder are two of the most common eating disorders. People with these difficulties find it hard to deal with how they feel and eat large amounts of food in a short period of time; this is called binge eating (Castillo & Weiselberg, 2017). People with Bulimia Nervosa often vomit after binge eating to avoid putting on weight. People who binge eat often feel very guilty and ashamed of their behaviour and are at a greater risk of experiencing mental health problems like depression and anxiety. There are different approaches to treating Bulimia Nervosa and Binge Eating Disorder but these are not always effective. Dialectical Behaviour Therapy is a psychological intervention that helps people to cope with difficult feelings without responding to these feelings and acting in ways that are problematic (Linehan, 1993).

Aim

The review aimed to summarise how much we know about Dialectical Behaviour Therapy and whether it reduces binge eating in people with Bulimia Nervosa and Binge Eating Disorder.

Method

All studies that measured the effectiveness of Dialectical Behaviour Therapy in reducing binge eating in people with Bulimia Nervosa and Binge Eating Disorder were identified at first; 14 relevant articles were then selected and rated on how good they were. The results of the articles were combined.

Results

The results showed that people with Bulimia Nervosa and Binge Eating Disorder, who received Dialectical Behaviour Therapy, used binge eating less frequently after taking part in the therapy. The effectiveness of Dialectical Behaviour Therapy was influenced by whether families were involved in the therapy and there were also differences in results depending on who delivered the therapy.

Conclusion

This review indicates that Dialectical Behaviour Therapy can help people with Bulimia Nervosa and Binge Eating Disorder to reduce binge eating. The review also highlights that how to best involve families in therapy and by who the therapy is delivered needs to thought of more carefully.

Children Overcoming Picky Eating (COPE) – A Cluster Randomised Control Trial

Background

Children who are reluctant to try new foods are sometimes described as picky or fussy eaters by their families and friends. Picky eaters are often reluctant to eat fruits and vegetables and can therefore struggle to have a healthy and varied diet that positively impacts on their health and well-being (Lafraire, Rioux, Giboreau, & Picard, 2016). Parents and other caregivers can therefore worry about their child's diet and how to best improve this. Being a picky eater can also negatively impact on a child's ability to enjoy everyday social events such as visits to restaurants or friends' birthday parties. To avoid these problems there are some interventions that can be used. For example offering new foods to children repeatedly so they are more familiar and being a role-model and eating new foods with children to show them that they are safe and edible/tasty. These approaches are not always successful in encouraging children to eat new foods and researchers have started to explore whether mindfulness may be helpful. Mindfulness is a state of mind that is characterised by paying attention to the present moment and associated thoughts, feelings and bodily sensations. It involves acknowledging these moment-by-moment, in a non-judgmental way and with open awareness (Kabat-Zinn, 2003).

Aim

The aim of this study was to find out whether children who practised mindfulness exercises at school over 5 days were more likely to expect a new fruit to taste nice and to eat more of it, than children who did not practise mindfulness.

Method

Seventy-one 10-12-year-olds took part. 23 children practised mindful breathing, 25 children practised mindful raisin-eating and 23 children engaged in a non-mindful control task (answering quiz questions and colouring). Children practised one of the three tasks at school over five days and were offered a new fruit on the final day. Children also filled in a number of forms on the first and final day of the study reporting on their mindfulness, picky eating and anxiety.

Results

The results showed that children who practised mindful raisin-eating expected that they would like the new fruit more than children who practised mindful breathing or engaged in a non-mindful task (Figure 1). Children who practised mindfulness also ate more of the new fruit than children who practised the non-mindful control task (Figure 2). There was no change in how children rated their mindfulness, picky eating and anxiety.

Conclusions

The results provide promising evidence that practising mindfulness, whether this involves breathing or eating a raisin, for 5 minutes over 5 days may help children to overcome their reluctance to try a new fruit. Mindful raisin-eating in particular may also help to improve children's expectations about the way a new fruit will taste. Whether these results can also be achieved with other foods like vegetables needs to be explored by future research.

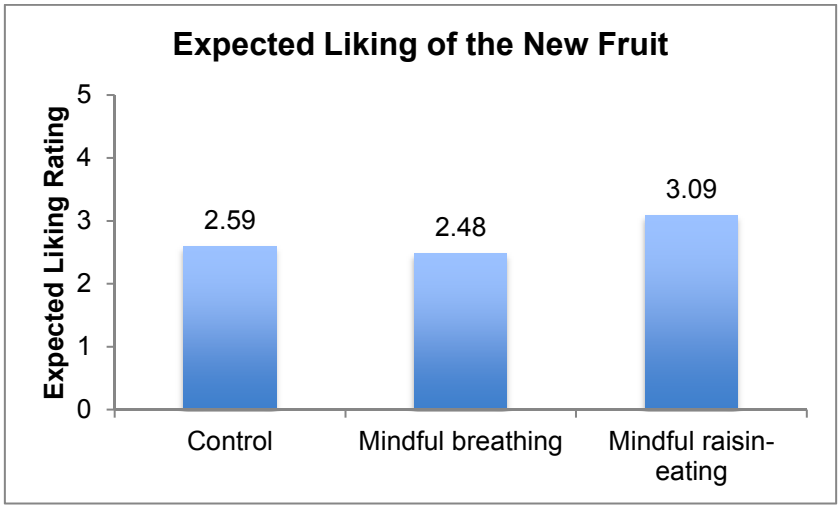

Figure 1. Expected liking rating given by children practising the control task, the mindful breathing task or the mindful raisin-eating task

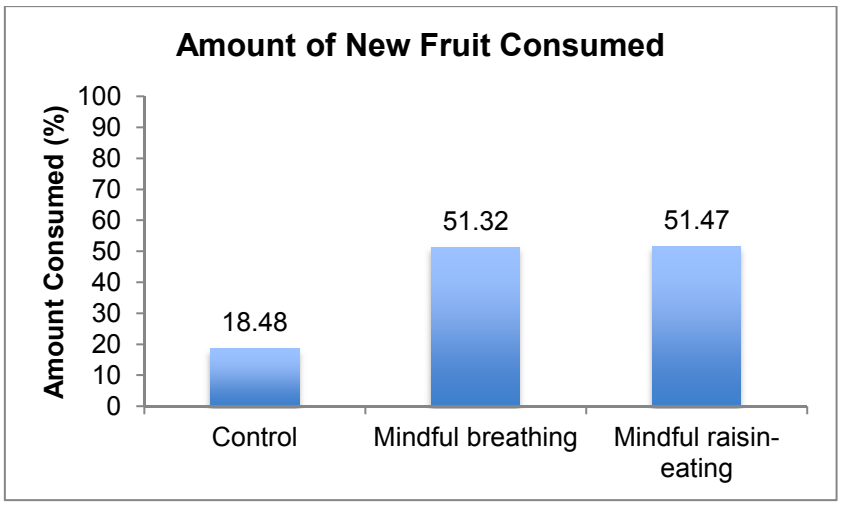

Figure 2. Amount of the new fruit consumed by children practising the control task, the mindful breathing task or the mindful raisin-eating task

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APPENDICES FOR VOLUME ONE

Appendix A

Overview of DSM-V criteria for BN and BED (APA, 2013; Castillo & Weiselberg, 2017)

Bulimia Nervosa	Binge Eating Disorder
Recurrent binge eating episodes: • Eating an amount of food over a discrete period of time (e.g. less than 2 hours) that is larger than other people would consume over the same period of time • Perceived loss of control over eating	Recurrent binge eating episodes: • Eating an amount of food over a discrete period of time (e.g. less than 2 hours) that is larger than other people would consume over the same period of time • Perceived loss of control over eating
Recurrent use of inappropriate compensatory behaviours to prevent weight gain, e.g. vomiting, using laxatives, diuretics, fasting or excessive exercise.	Absence of extreme weight compensatory behaviours seen in BN.
Binge eating episodes and compensatory behaviours do not exclusively occur during episodes of AN.	Binge eating episodes do not occur exclusively during the course of BN or AN.
Recurrent binge eating episodes and compensatory behaviours occurring, on average, at least once per week for at least three months.	Recurrent binge eating episodes occurring, on average, at least once per week for at least three months.
Severity of compensatory behaviours: • Mild: 1 to 3 episodes per week • Moderate: 4 to 7 episodes per week • Severe: 8 to13 episodes per week • Extreme: 14 or more episodes per week	Severity of bingeing eating episodes: • Mild: 1 to 3 episodes per week • Moderate: 4 to 7 episodes per week • Severe: 8 to13 episodes per week • Extreme: 14 or more episodes per week
	Presence of at least three of five behavioural indicators of loss of control over eating during binge eating episodes: 1. Eating more rapidly than normal 2. Eating until feeling uncomfortably full 3. Eating in the absence of hunger 4. Eating alone due to embarrassment about the quantity of food consumed 5. Feeling disgusted with oneself, depressed or very guilty after the binge eating episode
	Experiencing significant distress about binge eating.
Self-evaluation is unduly influenced by body shape and weight.	

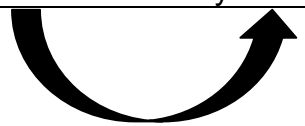
Appendix B

Overview of NICE-recommended psychological treatments for adults and children with BN and BED

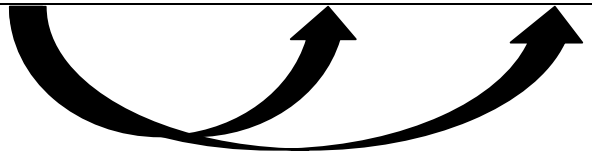
Table A

NICE-recommended psychological treatments for adults with BN and BED and suggested treatment focus, duration and intensity

BN		**BED**		
BN-focused guided self-help * Cognitive behavioural materials * Can be supplemented with brief support sessions (e.g. 4-9 20-minute sessions over 4 months)	Individual CBT-ED * Engagement and education * Support/advice to reintroduce regular eating patterns * Addressing underlying psychopathology * Maintenance and relapse prevention towards the end *If appropriate, involvement of significant others * 20 sessions over 20 weeks, initially twice weekly	BED-focused cognitive behavioural guided self-help * Focus on adherence to self-help programme * Can be supplemented with brief support sessions (e.g. 4-9 20-minute sessions over 4 months)	Group CBT-ED * 16 weekly 90-minute group sessions * Psychoeducation * Self-monitoring * Goal setting * Meal planning * Trigger identification * Body exposure training * Relapse prevention	Individual CBT-ED Described under BN



If unacceptable, contraindicated or ineffective

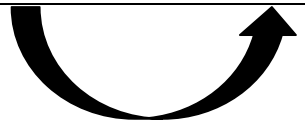


If unacceptable, contraindicated or ineffective – dependent on preference and availability

Table B

NICE-recommended psychological treatments for children with BN and BED and suggested treatment focus, duration and intensity

BN		**BED**
BN-focused Family Therapy * Good therapeutic relationship, non-blaming and collaborative approach * Role of family in recovery and support planning * Psychoeducation, reintroducing regular eating patterns, self-monitoring * Individual meetings with client and involvement of family members not part of FT if indicated * Relapse prevention and planning * 18-20 sessions over 24 weeks	Individual CBT-ED * If appropriate, involvement of carers (<4 sessions) for psychoeducation, exploration of family factors maintaining difficulties and support planning * Role of BN and motivation for change * Psychoeducation, formulation and reintroduction of regular eating patterns * Monitoring of thoughts/feelings/behaviours * Goal setting, problem-solving to address dysfunctional thoughts/behaviours * Relapse prevention * 18 sessions over 24 weeks	See above



If unacceptable, contraindicated or ineffective

Appendix C

Outline of factors potentially impacting on the meta-analytic effect and to be explored in sensitivity analyses

Moderator/sub-group	Variable Type	Description
Study Design	Categorical	• Between-Subject Design • Within-Subject Design
Trial Type	Categorical	• RCT • Pre-Post Comparison • Uncontrolled Pre-Post Comparison
Diagnosis	Categorical	• BN • BED • Both
Borderline Personality Disorder	Categorical	• Yes • No
Psychotropic Medication	Categorical	• Yes • No
Concurrent Therapy	Categorical	• Yes • No
Outcome measure	Categorical	• Eating Disorders Examination • Other Outcome Measure
Intervention Mode	Categorical	• Standard DBT • Group DBT • Group & Telephone Coaching • Guided SH • Individual DBT
Payment for Therapy	Categorical	• Yes • No
Family Involvement	Categorical	• Yes • No
Therapist qualification	Categorical	• Masters Level Qualification • Doctoral Level Qualification • Mixed Therapist Team • Qualified Psychologist • Qualified Psychiatrist
Sample Size	Continuous	Number of participants
Age	Continuous	Participant age
Ethnicity	Continuous	Proportion of sample identifying as Caucasian
BMI	Continuous	Participant BMI
Full-Threshold	Continuous	Proportion of sample meeting full-threshold criteria for BN or BED (or paediatric equivalent)
Eating Disorder Duration	Continuous	Self-reported duration of the eating disorder
Intervention Intensity (h p/w)	Continuous	Hours of intervention offered per week
Intervention Duration	Continuous	Duration of the intervention in months
Publication Year	Continuous	Year research was published
Quality Rating	Continuous	Quality rating generated by applying the quality framework

Appendix D

School invitation letters

Investigating eating behaviour in school-aged children

Children Overcoming Picky Eating (COPE):

Dear XX XXXX,

We are inviting you to participate in a research study.

What is the study about?
We are interested in children's eating behaviour, particularly what makes children more likely to try unfamiliar, new foods. Children who are reluctant to try new foods are sometimes described as picky or fussy eaters by their families and friends. Picky eaters are often reluctant to eat fruits and vegetables and can therefore struggle to have a healthy and varied diet that positively impacts on their health and well-being. Parents and other caregivers can therefore worry about their child's diet and how to best improve this. Being a picky eater can also negatively impact on a child's ability to enjoy everyday social events such as visits to restaurants or friends' birthday parties. We want to see whether a brief mindfulness-based exercise can help children to overcome their reluctance to try new food. Mindfulness is a state of mind that is characterised by paying attention to the present moment and associated thoughts, feelings and bodily sensations. It involves acknowledging these moment-by-moment, in a non-judgmental way and with open awareness. Mindfulness has its roots in ancient meditation practices but has been increasingly used in western healthcare approaches; people do not have to be religious or spiritual to use mindfulness-based exercises. Mindfulness exercises might help children to try new foods. Mindfulness programs are currently being rolled out across many schools in the UK.

Who can take part?
We are looking for a school that has three separate classrooms of children aged 10 to 12 years. All children in these classrooms and age groups will be eligible to take part. In addition to your consent to carry out this research in your school we will ask all parents and their children in these classrooms for consent. Participating children do not need to be picky eaters to take part; we are including children in the study whether they are fussy eaters or not. Hence, we are interested in the influence of a brief mindfulness-based exercise on the diet of children who are picky eaters but also of those who are not picky at all and like trying new foods.
Some children will not be able to take part in this research study. If a child or anyone in their immediate family has a food allergy, this child will not be able to take part in the study.

Do children have to take part?
Participation in this research study is voluntary. Children's parents do not have to consent to their child participating. Children will also be asked for their consent to participate. If parents and their children consent to participate in this research study, they will have the right to withdraw from participating at any time, without providing a reason. Not consenting for their child to participate or withdrawing from participation at any point will not have any negative

consequences for parents or their children. Children who are not taking part should not feel disadvantaged. We suggest that they are supervised while engaging in school-related work or with our educational colouring book outside of the classroom during the 5-minute mindfulness exercise. If fewer than five children in any of the identified classrooms consent to participate, it will not be feasible to run the research study and the researchers would have to withdraw the offer to run the study at your school.

What will classroom teachers and children have to do if I agree for this research to take place at my school?
The classrooms of children whose parents consent for them to participate in this research study will be randomly allocated to one of three study groups. Children in each of the three identified classrooms will engage in one of three tasks over five days (Monday to Friday); this will be either a 5-minute mindful raisin-eating exercise that will involve eating 1 raisin, a 5-minute mindful breathing exercise that will involve focusing one ones breath, or a 5-minute food education exercise that will involve learning food facts and colouring in fruits and vegetables. The task will be introduced by the researcher/team at the start of the week (Monday) and the researcher/team will ask children to complete a few short questionnaires on their hunger and reluctance to try new foods, their way of thinking, and tendency to worry. Classroom teachers will be asked to administer one of the three tasks (Tuesday/Wednesday/Thursday) by playing the mindfulness recording or handing out food education exercise booklet for 5 minutes at the start of the day. Finally, the researcher/team will return on the final day (Friday) to re-administer the questionnaires and to offer children an unfamiliar fruit they have never tried before. Children will not have to try this fruit if they do not want to.

What are the possible disadvantages and risks of taking part?
There are very few risks associated with this research. The main risk is food allergy, which is why we do not include anyone in the study where there is food allergy in the immediate family. We never serve food items containing nuts. All researchers have been Disclosure and Barring Service (DBS) checked (previously Criminal Records Bureau, CRB). You can speak to a member of the research team if you are concerned. Sources of support for e.g. eating problems and parenting will be listed for children and parents in a debrief sheet at the end of the study.

What are the possible benefits of taking part?
There are no major benefits to your school, parents or children for taking part in this research study. We can, however, offer £50 book vouchers to schools as a thank you for their support. Your participation may also help us to find out the best ways of helping children to overcome their reluctance to try unfamiliar, new foods to help them have a healthy and varied diet. At the end of the study children will be offered to choose from a range of stickers as a thank you for taking part in this research study.

What happens when the research study stops?
After the research study has finished we will write up the study's results and will provide you with a copy of the outcomes.

Will the school's and family's participation be kept confidential?
All the information you, parents and children provide to us is private and confidential. A database linking children's names and new food selection will be created to allow the researcher/team to provide the appropriate new food to be offered to children for sampling. This database will be deleted once the study has been completed. We do publish scientific articles using the data provided but it is never possible to identify any individual. Parents' and children's questionnaire data is also kept in a locked cabinet on university premises. This raw

data is kept for ten years, before being shredded. A database of the raw data is also made and kept on secure, password-protected PCs. Only the person in charge of the study, and her research team, has access to this database.

What if I have any questions?
If you have any questions about the research study please email Dr Carmel Bennett ( ) who will be happy to discuss the research study and answer any of your questions.

What if I am happy for my school to take part in this research study?
If you are happy for your school to participate in this research study please contact the lead researcher Dr Carmel Bennett ( ) to discuss the research and any questions you may have and possible dates for your school's participation.

Thank you for considering taking part in our research

Yours sincerely,
Carmel Bennett

Appendix E

Parent and child information sheets and consent forms

Investigating eating behaviour in school-aged children

Children Overcoming Picky Eating (COPE):

Parent Information Leaflet

We are inviting you and your child to participate in a research study.

What is the study about?
We are interested in children's eating behaviour, particularly what makes children more likely to try unfamiliar, new foods. Children who are reluctant to try new foods are sometimes described as picky or fussy eaters by their families and friends. Picky eaters are often reluctant to eat fruits and vegetables and can therefore struggle to have a healthy and varied diet that positively impacts on their health and well-being. Parents and other caregivers can therefore worry about their child's diet and how to best improve this. Being a picky eater can also negatively impact on a child's ability to enjoy everyday social events such as visits to restaurants or friends' birthday parties. We want to see whether a brief mindfulness-based exercise can help children to overcome their reluctance to try new food. Mindfulness is a state of mind that is characterised by paying attention to the present moment and associated thoughts, feelings and bodily sensations. It involves acknowledging these moment-by-moment, in a non-judgmental way and with open awareness. Mindfulness has its roots in ancient meditation practices but has been increasingly used in western healthcare approaches; people do not have to be religious or spiritual to use mindfulness-based exercises. Mindfulness exercises might help children to try new foods.

Why has my child been chosen?
All children aged 10 to 12 years, who attend (*name of school*) school, are eligible to take part in this research study. Your child's classroom is one of the classrooms that have been selected. All parents of children in this classroom have been asked whether they are willing to let their child participate in this research study. Your child does not need to be a picky eater to take part; we are including children in the study whether they are fussy eaters or not. Hence, we are interested in the influence of a brief mindfulness-based exercise on the diet of children who are picky eaters but also of those who are not picky at all and like trying new foods.

Some children will not be able to take part in this research study. If your child or anyone in your immediate family has a food allergy, your child will not be able to take part in the study.

Does my child have to take part?
Participation in this research study is voluntary. You do not have to consent to your child participating. Your child will also be asked for their consent to participate. If you and your child consent to participate in this research study, you will have the right to withdraw from participating at any time, without providing a reason. Not consenting for your child to participate or withdrawing from participation at any point will not have any negative consequences for you or your child. If fewer than five children in any of the identified classrooms consent to participate, it will not be feasible to run the research study and the researchers would have to withdraw the offer to run the study at your child's school.

What will happen to my child if he/she takes part?
The classrooms of children whose parents consent for them to participate in this research study will be randomly allocated to one of three study groups. Your child's classroom will either engage a 5-minute mindful raisin-eating exercise that will involve eating 1 raisin, a 5-minute mindful breathing exercise that will involve focusing one ones breath, or a 5-minute food education exercise that will involve learning food facts and colouring in fruits and vegetables. Your child will engage in one of these brief, 5-minute tasks on each day over the course of one week. Your child will also complete a few short questionnaires on his/her hunger and reluctance to try new foods, his/her way of thinking, and tendency to worry. Finally, your child will be offered an unfamiliar fruit he/she has never tried before. Your child will not have to try this fruit if he/she does not want to.

What will my child have to do?
Your child will be asked to engage in one of the mindfulness or food education exercises for 5 minutes each day over the course of a week (Monday to Friday) and to complete a few short questionnaires. The research team and the classroom teacher will support your child with this. Your child will also be given the opportunity to sample an unfamiliar, new fruit.

What are the possible disadvantages and risks of taking part?
There are very few risks associated with this research. The main risk is food allergy, which is why we do not include anyone in the study where there is food allergy in the immediate family. We never serve food items containing nuts. All researchers have been Disclosure and Barring Service (DBS) checked (previously Criminal Records Bureau, CRB). You can speak to a member of the research team if you are concerned. Sources of support for eating problems and parenting will be listed for you in a sheet to take home after the study.

What are the possible benefits of taking part?
There are no major benefits to your child for taking part in this research study, however, your participation may help us to find out the best ways of helping children to overcome their reluctance to try unfamiliar, new foods to help them have a healthy and varied diet. At the end of the study your child will be offered to choose from a range of stickers as a thank you for taking part in this research study.

What happens when the research study stops?
After the research study has finished we will write up the study's results and will provide your child's school with a copy of the outcomes for you to access.

Will my child's taking part in the study be kept confidential?
All the information you provide to us is private and confidential. A database linking your child's name and new food selection will be created to allow the researcher to provide the appropriate new food to be offered to your child for sampling. This database will be deleted once the study has been completed. We do publish scientific articles using the data you provide but it is never possible to identify any individual. Your and your child's questionnaire data is also kept in a locked cabinet on university premises. This raw data is kept for ten years, before being shredded. A database of the raw data is also made and kept on secure, password-protected PCs. Only the person in charge of the study, and her research team, has access to this database.

What if I have any questions?
If you have any questions about the research study please email Dr Carmel Bennett ( ) who will be happy to discuss the research study and answer any of your questions.

What if I am happy for my child to take part in this research study?
If you are happy for your child to participate in this research study please complete the enclosed parent consent form, the screening form and brief questionnaire. Please also discuss the child information sheet and complete the child consent form with your child. Once completed please place all these forms into the enclosed envelope and return them to your child's teacher, who will collect them and will pass them to the researcher. Please return these forms by XX/XX/XXXX (*2 weeks after information packs given*).

Thanks for considering taking part in our research.

UNIVERSITY OF BIRMINGHAM

Investigating eating behaviour in school-aged children
Children Overcoming Picky Eating (COPE):
Information Sheet for Children

You are invited to take part in a research study looking at eating behaviour. The decision to take part is up to you. In this research study, we are looking for ways to help children to overcome picky eating.

What will I have to do?
If you decide to take part you, together with the other children in your classroom, will complete a short task with your teacher every morning for one week. The task will either be exploring and eating a raisin, a calm breathing exercise or reading food facts and colouring. You and the other children in your class will only complete one of these tasks. The task will last 5 minutes each day. You will also complete forms looking at your eating behaviour, how hungry you are and how you think, feel and act. You can also try a new fruit at the end of the week. You will not have to eat this fruit if you do not want to.

What's bad about taking part?
There is nothing bad about taking part in this research study. If you or someone in your close family, however, suffer from a food allergy you will not be able to take part to keep you safe.

What's good about taking part?
If you decide to take part in this research study we will understand more about how to help children who do not like to try new foods. You will also be able to choose from a range of stickers at the end of the week.

What will happen to the information I give you?
All the information you give us in this research study will stay private. Nobody except for the person helping you to complete your forms and the researcher will see your answers.

Do I have to take part?
Taking part in this research study is voluntary. You can stop taking part at any time. Nothing bad will happen if you decide not to take part or want to stop taking part. If you would like to stop taking part at any point during the research study please tell your teacher.
If you have any further questions please speak to your teacher, carer or contact the researcher Dr Carmel Bennett via email: [redacted] She is happy to answer your questions about this research study.

UNIVERSITY OF BIRMINGHAM

Participant code:

Investigating eating behaviour in school-aged children

Children Overcoming Picky Eating (COPE):

Parent Consent Form

I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. (Please tick the box). ☐

I understand that my/my child's participation is voluntary and that I am/my child is free to withdraw at any time without giving any reason, without negative consequences. (Please tick the box). ☐

I hereby give my consent for my child .....(insert name here) to take part in the University of Birmingham's study: Children Overcoming Picky Eating (COPE). I confirm that my child and his/her immediate relatives do not have any known food allergies and I have completed the enclosed Screening Form and Brief Demographic Questionnaire. (Please tick the box). ☐

We may contact some parents, asking them to complete a further brief questionnaire. If you would be happy to be contacted please tick this box and provide your address below so we can send the questionnaire to you directly.

Name of parent/guardian.....

Address (if happy to complete further questionnaires).....

.....

Signed.....

Date.....

Researcher.....

Signed.....

Date.....

UNIVERSITY OF BIRMINGHAM

Participant code:

Investigating eating behaviour in school-aged children
Children Overcoming Picky Eating (COPE):
Consent Form for Children

I would like to take part in the research study titled:
Children Overcoming Picky Eating (COPE).
(Please circle your answer).

I have read and understood the information leaflet.
I know what the study is about and what I will be asked to do.
(Please circle your answer).

I know that I do not have to take part and that I can decide to stop taking part at any time.
(Please circle your answer)

Child's Name.....

Date.....

Researcher's name.....

Researcher's Signature.....

Date.....

Appendix F

Parent debrief sheets

UNIVERSITY OF BIRMINGHAM

Participant code:

Investigating eating behaviour in school-aged children
Children Overcoming Picky Eating (COPE):
Parent Debrief Sheet

What was the study about?
We were examining whether mindfulness can help children to overcome their reluctance to try unfamiliar, new foods to help them have a healthy and varied diet. We will also be relating your child's responses to a new fruit to the questionnaire responses you and your child have given. The children who are taking part in this study were allocated to one of three study groups. Your child's classroom either engaged in a 5-minute mindful raisin-eating exercise that involved eating one raisin, a 5-minute mindful breathing exercise that involved focusing one ones breath, or a 5-minute food education exercise that involved learning food facts and colouring in fruits and vegetables. Your child engaged in one of these brief, 5-minute tasks on each day over the course of one week. By seeing how children differ in their willingness to try a new food (fruit) at the end of the week we may be able to understand whether mindfulness-based approaches can be helpful to encourage children to try new foods and what type of mindfulness-based exercises may be most helpful. Your questionnaire responses will help us to understand the underlying mechanisms for this further.

All the information you have given us is private and confidential and will be securely stored. You can withdraw the data you have provided to us at any time, until the data have been submitted for publication. Information on the study's outcomes and any resulting publications will be passed on to your school, which will share this information with you.

Thank you for taking part in our research.

If taking part in this study has raised some concerns for you, you may like to contact one of the following sources of support:

You can ask your **GP or School Nurse** for advice if your child's weight or eating is causing you concern.

If taking part in this study has raised any concerns about your own eating, you may want to contact **BEAT eating disorders**: a charity for anyone affected by an eating problem. http://www.b-eat.co.uk / 0845 634 1414.

For information and support for parenting, you may wish to contact Parentline, a charity providing help and support for anyone caring for children. http://www.parentlineplus.org.uk / 0808 800 2222

If you have any further questions please don't hesitate to contact
Dr Carmel Bennett, Trainee Clinical Psychologist, School of Psychology, University of Birmingham**,** e-mail: .

Appendix G

Food Facts Booklet for Children in the Control Arm of the Trial

UNIVERSITY OF BIRMINGHAM

Name:

Investigating eating behaviour in school-aged children

Children Overcoming Picky Eating (COPE):

Educational Colouring Book

FOOD FACTS FOR KIDS!

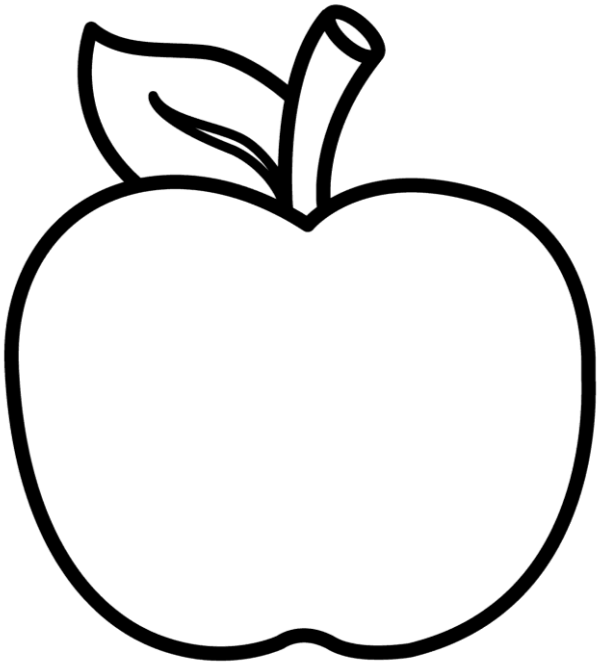
DID YOU KNOW...?



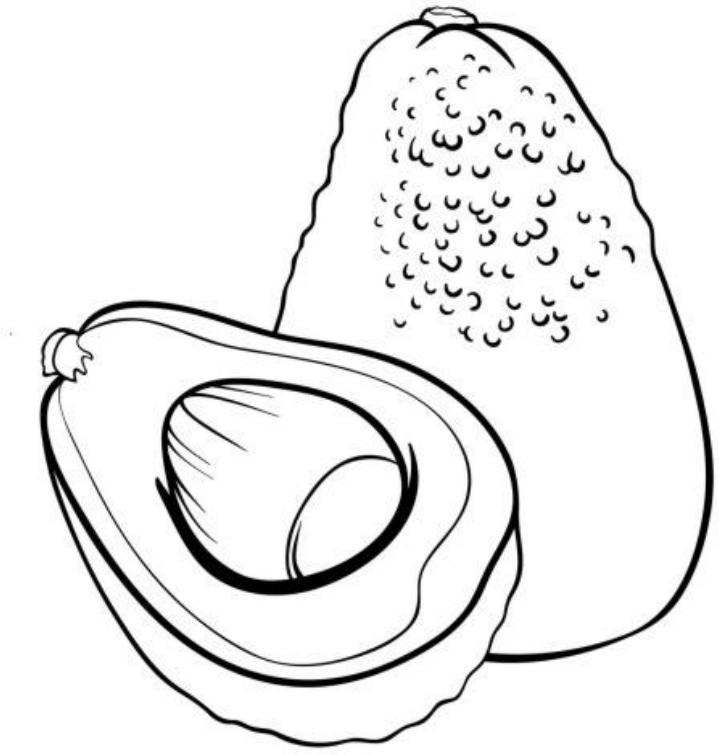

Please complete two pages each day.

Read the food facts, colour in the fruits and vegetables and complete the food quiz.

Apples are made of 25% air that is why they float.



Avocado has the highest protein and oil content of all fruits, but most of this is the healthier unsaturated type.



1. The rice dish ‘paella’ comes from what country?

(Please circle your answer)

(a) Germany (b) China (c) Spain

2. From which country do potatoes originate?

(Please circle your answer)

(a) Ireland (b) South America (c) Greenland

3. Which fruit comes in varieties known as Granny Smith and Pink Lady? (Please circle your answer)

(a) Grapefruit (b) Pears (c) Apples

4. What food is used as the base of guacamole?

(Please write down your answer).....

5. The range of vegetables, fruits, meats, nuts, grains, herbs and spices used in cooking is known as what?

(Please circle your answer)

(a) Signs (b) Ingredients (c) Samples

The water content of green Cabbage is 93%.

Carrots were originally purple in colour, changing in the 17th Century to orange with newer varieties.

Tuesday (Day 2)

1. True or false? India is the largest producer of bananas. (Please circle your answer)

True False

2. What is the sweet substance made by bees?

(Please write down your answer).....

3. Is it healthier to eat an apple or to drink a glass of apple juice?

(a) To eat an apple (b) To drink a glass of apple juice

4. Which spice can be unhealthy if you eat too much of it?

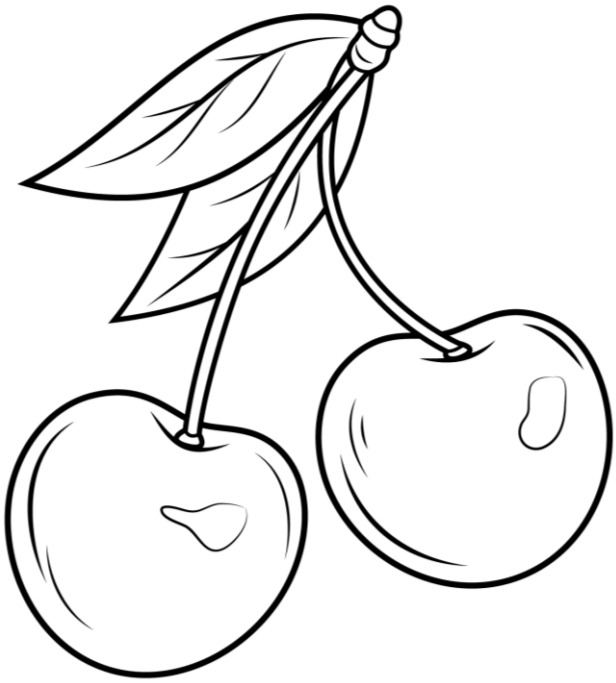
(a) Pepper (b) Garlic (c) Salt

5. A dried plum is properly known as a .....?

(Please circle your answer)

(a) Prune (b) Raisin (c) Date

Cherries are a member of the rose family.



Corn always has an even number of rows on each ear. Corn makes up about 8% of the weight in a box of corn flakes.

Wednesday (Day 3)

1. Foods rich in starch such as pasta and bread are often known by what word? (Please circle your answer)

(a) Protein (b) Carbohydrates (c) Fat

2. Which one of these fruits is usually not sweet?

(Please circle your answer)

(a) Mangoes (b) Pineapple (c) Lemons

3. What is another name for maize?

(Please write down your answer).....

4. Fruit preserves made from citrus fruits, sugar and water are known as what? (Please write down your answer)

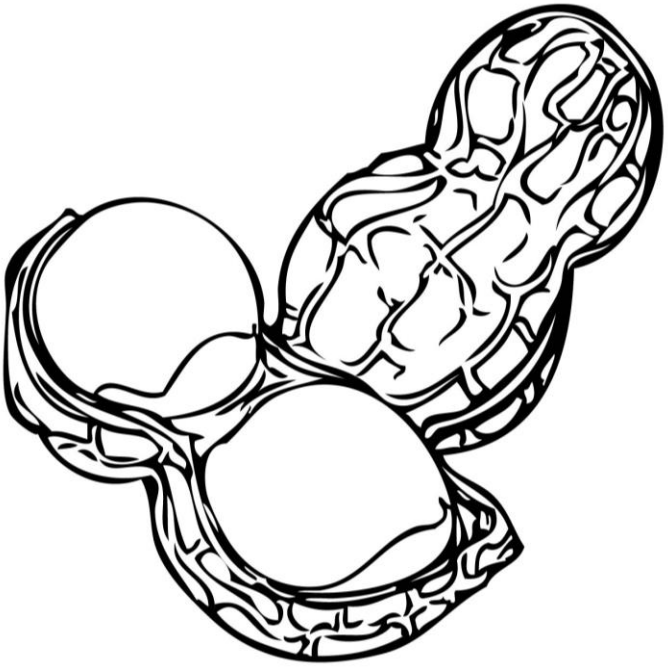
.....

5. A tomato is a .....?

(a) Fruit (b) Vegetable (c) Herb

Orange trees can grow to reach 30 feet and live for over a hundred years.

Peanuts are legumes and not a tree nut. Peanuts actually grow underground, as opposed to nuts like walnuts or almonds that grow on trees.



Thursday (Day 4)

1. Dairy products are generally made from what common liquid?

(Please write down your answer).....

2. True or false? Coconut trees grow better in cold climates? (Please circle your answer)

True **False**

3. What color are oranges before they are ripe?

(a) Blue **(b) Red** **(c) Green**

4. What is the popular food used to carve lanterns during Halloween?

(Please circle your answer)

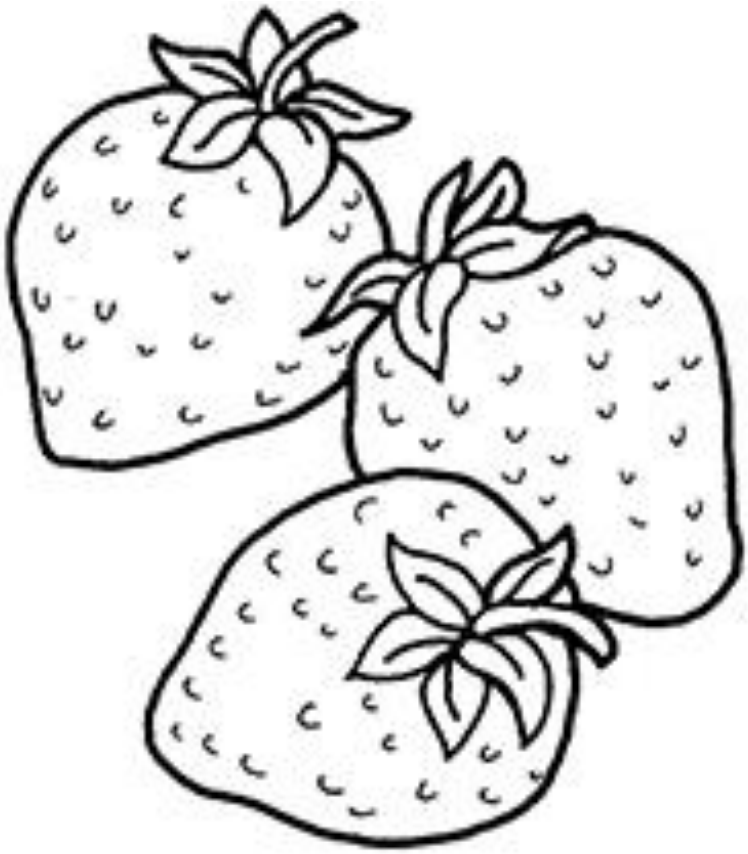
(a) Apples **(b) Pumpkins** **(c) Cucumber**

5. Chiffon, marble and bundt are types of what?

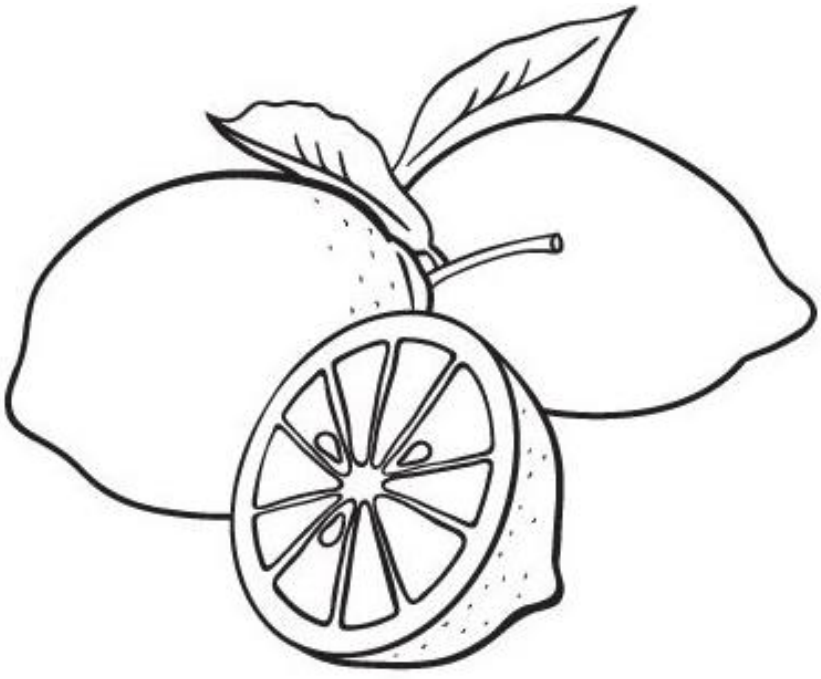
(Please circle your answer)

(a) Fish **(b) Cabbage** **(c) Cake**

Strawberries are the only fruit that has seeds on the outside. The fruits are high in vitamin C.



Lemons contain more sugar than strawberries.



Friday (Day 5)

1. I am a vegetable that is yellow. I can come in many different forms, like on the cob, or as kernels in a can. What vegetable am I?

(a) Green beans (b) Broccoli (c) Corn (sweetcorn or maize)

2. True or false? 'Beefsteak' is a variety of tomato.

(Please circle your answer)

True False

3. I am a fruit. I am yellow. Monkeys like to eat me and so do humans. What am I? (Please circle your answer)

(a) Apple (b) Banana (c) Grape

4. Lures reels, rods, hooks, baits and nets are common equipment used in what food gathering method?

(Please write down your answer).....

5. Strawberries, raspberries, peaches and cherries are all related to which type of flower?

(a) The rose (b) The daffodil (c) The lily

Food Quiz Answers

Day 1
1. (c) Spain
2. (b) South America
3. (c) Apples
4. Avocado
5. (b) Ingredients

Day 2
1. True
2. Honey
3. (a) To eat an apple
4. (c) Salt
5. (a) Prune

Day 3
1. (b) Carbohydrates
2. (c) Lemons
3. Sweetcorn or Corn
4. Marmalade
5. (a) Fruit (although for cooking purposes they are quite often described as vegetables)

Day 4
1. Milk
2. False
3. (c) Green
4. (b) Pumpkins
5. (c) Cake

Day 5
1. (c) Corn (sweetcorn or maize)
2. True
3. (b) Banana
4. Fishing
5. (a) The rose

Appendix H

Anticipated liking Scale

UNIVERSITY OF BIRMINGHAM

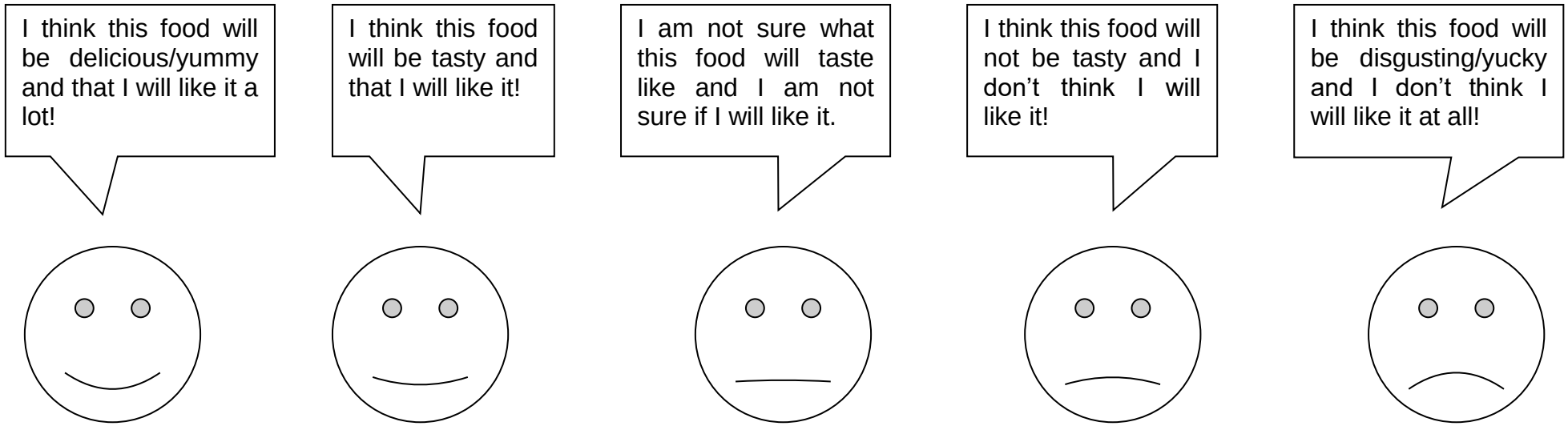
Investigating eating behaviour in school-aged children

Children Overcoming Picky Eating (COPE)

Anticipated Liking Scale

Participant code:

How much do you think you will like this new fruit?



Appendix I

Screening Form and Brief Questionnaire

Participant code:

Investigating eating behaviour in school-aged children

Children Overcoming Picky Eating (COPE):

Screening Form and Brief Questionnaire

Thank you for agreeing to be part of this study, which explores the impact of mindfulness on picky eating and the reluctance to try new food in children. Please complete the screening questions below to ensure that we are aware of any food allergies your child may have and what fruits your child has eaten before. On the back of this page you will find a brief demographic questionnaire. Please complete this, as it will allow us to know a bit more about the children who are participating in this research study. Thank you!

2. This study explores whether mindfulness can help children overcome their reluctance to try new foods. We would therefore like to know what types of fruits your child has previously eaten before.
Please indicate, for each of the fruits listed below, if your child **HAS** or **HAS NOT** tried this fruit before. Please indicate this by placing a tick in the relevant column.

	My child **HAS** tried this fruit	My child **HAS NOT** tried this fruit before
Dried		
Fresh fig		
Sharon fruit		
Dragon fruit		
Physalis		
Fresh/canned lychee		

If your child has eaten all of the above fruits before, please name any other fruits that your child has not previously eaten:……..……
……

Brief Demographic Questionnaire

3. What is **your child's** month and year of birth? _____

4. What is **your child's** gender? (Please tick):

☐ Male ☐ Female ☐ Other (please describe):

5. What is **your** month and year of birth? _____

6. What is **your** gender? (Please tick):

☐ Male ☐ Female ☐ Other (please describe):

7. What is your relation to this child? (Please tick)

Parent ☐ Step-parent ☐ Guardian ☐ Other:

8. Please tick the category that best describes your ethnic background:

☐ White British/Caucasian ☐ Black British/Black

☐ Asian British/Asian

☐ Mixed background (please describe): Other (please describe):

_____ _____

9. Which of the following categories best describes your **total** annual household income?

Under £15,000 ☐ £15,000-£30,000 ☐ £30,000-£45,000 ☐

£45,000-£60,000 ☐ £60,000-£75,000 ☐ £75,000+ ☐

10. Which of the following best describes your educational background?

(Please tick only your highest qualification)

☐ Some secondary school education ☐ Higher Degree (e.g. MA or PGCE)

☐ O Levels, CSEs or GCSEs ☐ Qualified Professional

☐ AS/A-levels or Higher School Certificate ☐ Other:_____

☐ University graduate (e.g. BSc or BA) ☐ No Qualifications

Thank you. Please place this brief questionnaire and the consent form into the envelope and return it to your child's teacher.

Appendix J

Information on Measures Sent to Parents for Completion and Relationships between Parent and Child Ratings of Food Neophobia and Anxiety

Food Neophobia. Parent-reported child food neophobia was measured using the Child Food Neophobia Scale (CFNS; Pliner, 1994). This 10-item scale measures parent-perceived child reluctance to try novel foods. Items are measured on a 7-point Likert scale ranging from 1 (*Disagree Strongly*) to 7 (*Agree Strongly*). The CFNS has been validated for use by parents with children as young as 4 years and has been found to be correlated with behavioural neophobia (Cooke, Carnell, & Wardle, 2006). The Cronbach's alpha reached .95 in the current study.

Anxiety. Child anxiety was measured using the parent-report version of the Spence Children's Anxiety Scale (SCAS-P; Nauta et al., 2004). The measure consists of 38 items that are closely linked to the items of the child self-report version of the measures. The SCAS-P measures six aspects of anxiety (Separation Anxiety, Social Phobia, OCD, Panic/Agoraphobia, Physical Injury and GAD) and items are measured on a 4-point Likert scale ranging from 0 (*Never*) to 3 (*Always*). The measure has good internal consistency scores for the individual subscales and overall scale and parent and child-reports are moderately linked (especially for observable rather than internalised behaviours; Nauta et al., 2004). The Cronbach's alpha reached .89 in the current study.

Partial correlations controlling for child age were carried out to explore the relationships between parent-reported (*N*=14) and child self-reported (*N*=71) food neophobia (Table A). As can be seen, parent- and child-reported neophobia were highly correlated so that parents who reported their child was high in neophobia had children who reported being less willing to try new foods/more neophobic. Partial

correlations controlling for child age were carried out to explore the relationships between parent-reported and child self-reported anxiety (Table A). Interestingly, parent- and child-reported anxiety were not associated.

Table A

Relationships between parent reported food neophobia and anxiety and child-reported levels of these factors at baseline and post-intervention

Child self-report measures	**Parent-reported Neophobia**	**Parent-reported Anxiety**
Baseline FSQ	-.72*	-
Post-intervention FSQ	-.71*	-
Baseline SCAS	-	.15
Post-intervention SCAS	-	.17

- $p<.05$

Appendix K

Demographic characteristics of the overall sample (*N*=71) broken down by trial arm

Variables	Control Group (*n*=23)	Mindful breathing group (*n*=23)	Mindful raisin-eating group (*n*=25)
Child gender	6 male, 17 female	8 male, 15 female	8 male, 17 female
Child age, mean (*SD*)	10.39 (.5)	10.35 (.57)	10.36 (.5)
Parent/Caregiver gender	5 male, 15 female	6 male, 16 female	4 male, 17 female
Parent/Caregiver age, mean (*SD*)	41.33 (8.39)	40.3 (7.5)	37.23 (6.08)
Relationship			
Parent	90.5% (*n*=19)	90.9% (*n*=20)	100% (*n*=25)
Legal guardian	4.8% (*n*=1)	4.5% (*n*=1)	N/A
Other	4.8% (*n*=1)	4.5% (*n*=1)	N/A
Educational level			
Qualified professional	5% (*n*=1)	9.5% (*n*=2)	5% (*n*=1)
University graduate	10% (*n*=2)	9.5% (*n*=2)	40% (*n*=8)
AS/A-Levels	15% (*n*=3)	19% (*n*=4)	20% (*n*=4)
O-Levels, CSEs or GCSEs	40% (*n*=8)	33.3% (*n*=7)	20% (*n*=4)
Some secondary education	N/A	19% (*n*=4)	10% (*n*=2)
Other			
No formal qualifications	15% (*n*=3)	4.8% (*n*=1)	5% (*n*=1)
	15% (*n*=3)	4.8% (*n*=1)	N/A
Annual household income			
£75000			
£60-75000	5.3% (*n*=1)	5.3% (*n*=1)	9.5% (*n*=2)
£45-60000	5.3% (*n*=1)	N/A	N/A
£30-45000	10.5% (*n*=)	N/A	N/A
£15-30000	15.8% (*n*=3)	15.8% (*n*=3)	38.1% (*n*=8)
< £15000	31.6% (*n*=6)	31.6% (*n*=6)	19% (*n*=4)
	31.6% (*n*=6)	47.4% (*n*=9)	33.3% (*n*=7)
Ethnicity			
White British	47.6% (*n*=10)	22.7% (*n*=5)	30.4% (*n*=7)
Black British	4.8% (*n*=1)	N/A	4.3% (*n*=1)
Asian/Asian British	38.1% (*n*=8)	72.7% (*n*=16)	39.1% (*n*=9)
Mixed	N/A	N/A	13% (*n*=3)
Other	9.5% (*n*=2)	4.5% (*n*=1)	13% (*n*=3)