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Protocol for a Cluster Randomised Controlled Trial to Compare the "Taste & See" Programme—A Church-Based Programme to Develop a Healthy Relationship with Food—With a Wait-List Control

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Abstract: (1) Background: Obesity is strongly associated with poor mental-health. Spiritual and religious wellbeing is associated with improved mental well-being and reduced emotional eating. "Taste & See", a church based programme to help develop a healthy relationship with food has been successfully tested for feasibility in the UK but an adequately powered randomised controlled trial is needed to test efficacy. This paper reports on the protocol for such a trial; (2) Method: A cluster, randomised controlled trial where Christian churches (any denomination) are the unit of randomisation. 150 overweight adults will be recruited from approximately 15 churches (clusters) in the UK, each church (cluster) will recruit approximately 10 participants. Churches will be randomised 2:1 to either begin the "Taste & See" programme immediately or in 10 weeks' time. Data on eating habits, mental and spiritual health will be collected online before and after the intervention and control period and follow-up will continue until 2 years; (3) Implication of Results: Should the programme prove effective it will provide strong clinical evidence of the role of churches in improving the health and well-being of those struggling with food and weight issues.

Keywords: obesity; weight; emotional eating; cluster randomized controlled trial; religious; spiritual; church; Christian; community; public health; intuitive eating

1. Introduction

Obesity is a global problem (Frühbeck and Yumuk 2014) and is strongly associated with poor mental-health (Luppino et al. 2010) which is perpetuated by obesity stigma within society (Puhl and Heuer 2009); therefore a compassionate and non-judgemental holistic intervention is particularly important. Good spiritual well-being has been associated with improved mental well-being (Koenig 2009) and reduced emotional eating (Hawks et al. 2003). Yet very little attention has been given to spiritual or religious considerations related to food and weight issues, or how churches in the UK may be able to help address these needs, within the community.

The "Taste & See" programme is an intervention which has been designed to do this; it combines the scientific evidence base of nutrition and the psychology of eating with the opportunity for religious engagement, whereby, freedom from guilt and shame, which accompanies weight loss failure, can be explored from a Christian perspective. "Taste & See" is an intervention that views obesity as a chronic, relapsing, remitting condition, and aims to reduce the harms associated with it; rather seeking weight loss at all costs. The design of the "Taste & See" programme and the protocol for testing the feasibility of this was previously reported in Religions (Lycett et al. 2016). The results of the feasibility study, also previously reported in Religions, showed this programme could be run successfully by church volunteers and improvements in participants' mental well-being, emotional eating and quality-of-life

were observed during and for six months after the programme (Patel et al. 2017a). An embedded qualitative study of participant experience on this programme showed participants journeyed from shame and guilt to acceptance and freedom (Patel et al. 2017b).

The feasibility study led to the development of a revised programme which could be rolled out more widely with ease and without dilution of the content. The programme is contained on a DVD, with an accompanying participant workbook and training manual for facilitators. The feasibility trial also provided data for sample size calculations for a superiority trial; this revised programme is now being tested in a multi-centre, cluster, randomised controlled trial. In keeping with good clinical practice and transparent scientific reporting the a priori protocol of this trial is described here.

2. Aim

To run a cluster randomised controlled trial on emotional eating to compare the effect of the "Taste & See" programme with a weight list control in those who are overweight or perceive themselves to have an unhealthy relationship with food.

3. Objectives

- To compare change in emotional eating and changes in other measures of psychological, spiritual and physical well-being, between those attending the "Taste & See" programme and those randomised to the wait list control, at the end of intervention;
- To investigate ongoing change in these variables at 6 months and 2 years;
- To assess the mediating associations between each of these variables and how well they fit the theoretical model that underpins intervention;
- To assess participant and facilitators acceptability of taking part in and facilitating the trial programme.

4. Methods

4.1. Study Design

To conduct a cluster, randomised controlled trial where Christian churches (of any denomination) are the unit of randomisation.

4.2. Ethics

Ethical approval has been provided by Coventry University Research Ethics Committee. The trial will be conducted in accordance with the ethical guidelines of the British Psychological Society and the recommendations for clinicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki, 1964, and later revisions. All of the data collected for this study will be treated confidentially and stored securely in accordance with the Data Protection Act 1998. No participants will be identifiable from the results of the study.

4.3. Participants

4.3.1. Inclusion Criteria

Non-pregnant, adults with a BMI over 25 kg/m^2 or if BMI is between 18.5 and 25 kg/m^2 they may be included if they perceive themselves to have an unhealthy relationship with food. Able to understand and consent to study procedures.

4.3.2. Exclusion Criteria

If weight loss has exceeded 2 kg in the last month, suffering from any medical condition with which it would be inadvisable to lose weight.

4.4. Study Setting and Recruitment

Recruitment of churches will be through known contacts and national church networks e.g., Parish nursing UK, The Baptist Union of Great Britain.

An email invitation will be sent to churches who will be invited to find out more about the programme and how to take part by clicking on the link to the "Taste & See" programme website (http://tastes.coventry.ac.uk). If the church wants to take part they designate a programme facilitator who will champion the programme. This facilitator will follow the following steps:

1. Decide on a weekly time to run the course, prepare two potential start dates: one to start as soon as interested participants have registered and the other scheduled to start 10 weeks later.
2. Advertise the programme in their church and local community. They will find on the website: a poster to print off insert local details and display, a 1 min advert about Taste and See and a 5 min trailer to give people more a feel for the programme.
3. Facilitators refer interested people to the website to read the participant information. Interested people give the facilitator their email or postal address & permission to share these details with the researchers.
4. The facilitator registers their church by completing the online registration form, confirming they have understood and agree to under-taking this role. They then insert the emails of all those who would like to do the programme.

Each potential participant then receives an email inviting them to re-read the participant information, consent to the research and complete the baseline questionnaire.

4.5. Randomisation

Once the participants have completed their baseline questionnaires randomisation will occur. Randomisation occurs after individual recruitment to avoid post-randomisation selection bias (Campbell et al. 2004). This will occur at the church level and not within a church, to avoid cross-contamination. A randomization sequence will be generated using computer software using blocking to ensure balance as the sample size for this trial is small. Churches will be randomized 1:2 to wait list control and intervention to minimise dissatisfaction of those in the control group (Figure 1). Allocation of randomisation will be sent by email to programme facilitators, in the generated sequence. Allocation is therefore concealed and cannot be sabotaged. Depending on the random allocation the programme then begins on the earliest start date or for the control group on the start date 10 weeks later.

4.6. Intervention Programme

The intervention has been developed on the theoretical underpinning which comes from the cycle of dieting and weight regain (Stroebe et al. 2013) (in red in Figure 2). To break that cycle the four principles of intuitive eating have been incorporated (in yellow in Figure 2), a unique layer of Christian principles from the bible that apply to breaking the cycle in this way has then been included (in green in Figure 2). The intervention consists of 10 weekly sessions which takes the participants on a journey from identifying problematic eating behaviours to begin making changes. The programme incorporates 25 behavior change technique (Michie et al. 2013) and is described more fully in the feasibility study protocol (Lycett et al. 2016). The programme resources have now been developed into a 'off the shelf' prototype package which is sent to churches to be delivered locally by the programme facilitators. The "Taste & See" programme is a free resource to churches and has been funded for research purposes. The package contains:

- The "Taste & See" DVD which containing a series of 10 sessions. The DVD presents both a scientific and a Christian viewpoint to the topics. The course is written by Deborah Lycett RD PhD (Reader in nutrition, dietetics and spiritual health); with Christian input from church members who have also been Taste & See facilitators (Rebekah Hodson, Elaine Davis) and this content

has been checked for theological accuracy to ecumenical Christian concepts by church ministers. Healthy eating tips are presented by Nicky Walker RD. Personal stories from those who have done the programme and offered to be filmed are also included in the DVD.

- The "Taste & See" Participant's Manual, this is a workbook which accompanies the "Taste & See" DVD so participants can document their reflections, their goals and the group discussions that take place each week. There are discussion prompts on the DVD so that issues raised can be discussed in small groups.
- The "Taste & See" Bible Meditations, this is a booklet of readings for daily inspiration throughout the programme.
- The "Taste & See" Facilitator's Manual, this is an instruction booklet for facilitators with a step by step guide on how to run the programme locally. It describes the course ethos and contains instructions on facilitating groups effectively, creating an emotionally safe and confidential group environment and when to refer people on to health professionals.

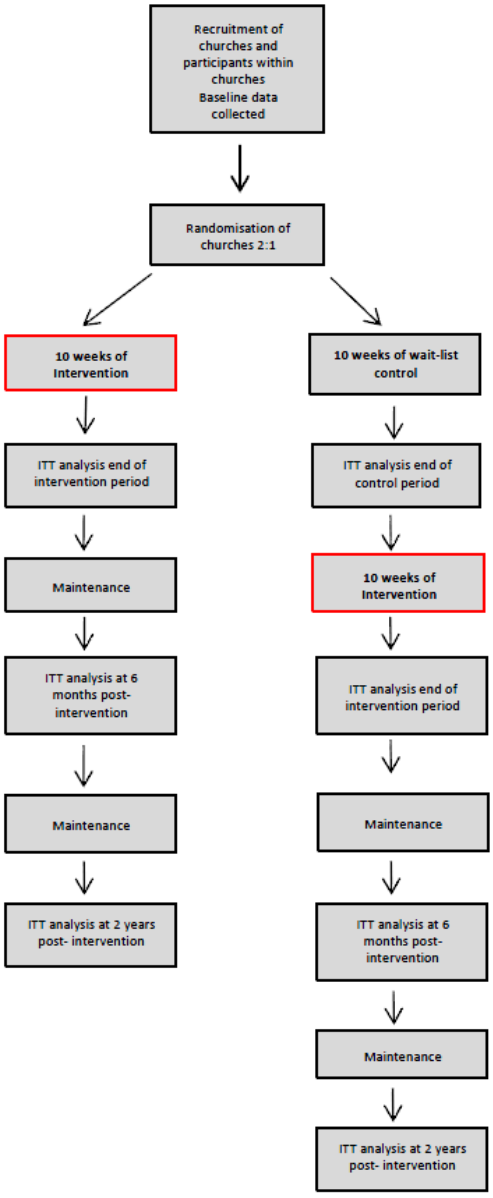

Figure 1. Consort diagram showing randomisation and path of participants through the trial.

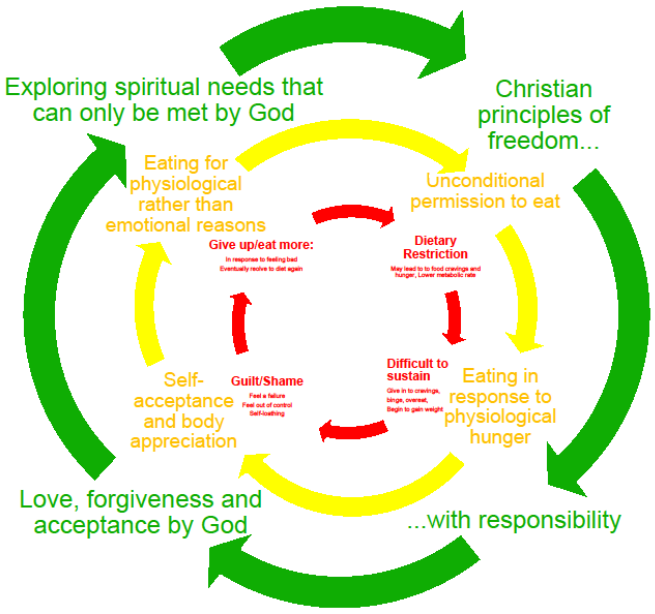

Figure 2. Theoretical underpinning of the intervention (Lycett et al. 2016).

4.7. Control Programme

The control programme is a delayed start or wait-list control. Those churches in the control group will be required to collect data at the time of randomisation, but the intervention will not begin until 10 weeks have passed.

4.8. Primary Outcome

This will be change in emotional eating from the beginning to the end of the intervention and will be compared to change in emotional eating during the waitlist control. This will be measured using the emotional eating domain of the three-factors eating questionnaire (TFEQ-R21) (Karlsson et al. 2000).

4.9. Secondary Outcomes

Emotional eating will be measured at 6 months and 2 years post-intervention. Change in weight, depression, anxiety, mental well-being, eating attitudes and behaviours, fruit and vegetable consumption, physical activity, quality of life, weight related guilt and shame, body satisfaction, religiosity, attitude to God, attachment to God, religious coping and spiritual experience will be measured, using the scales described below, from the beginning to the end of the intervention and will be compared between the intervention and control. These measures will also be taken at 6 months and 2 years post-intervention.

4.10. Process Outcomes

All of the above variables measure a different dimension in the theoretical model that underpins the intervention. In line with the process measure objective to explore the mechanism by which this intervention works, the data collected from these scales will be included in a mediation and path analysis test how well whether the results maps onto the theoretical cycle.

Acceptability will be measured before, during and after the intervention.

4.11. Outcome Measures

All measurement except for demographics (taken at baseline only) will be collected at baseline, at the end of the intervention or control period, after 6 months and at 2 years follow-up. Data will be

collected via a secure online database (Bristol Online Survey), into which participants directly enter their data, with help if needed, from their local facilitators. Outcome measures include: self-reported height and weight; depression which will be measured using the Patient Health Questionnaire (PHQ-9) (Kroenke and Spitzer 2002); anxiety will be measured using the Generalised Anxiety Disorder (GAD-7) questionnaire (Spitzer et al. 2006), Mental well-being will be measured using the Warwick- Edinburgh mental well-being scale (WEMWBS) (Tennant et al. 2007); eating behavior using the three-factors eating questionnaire (TFEQ-R21) (Karlsson et al. 2000) and intuitive eating scale (Tylka and Kroon van Diest 2013); health-related quality of life (QoL) using EQ-5D (Herdman et al. 2011); weight-related quality of life using the Obesity Adjustment Survey—short form (OAS-SF) (Butler et al. 1999) and the weight and body related shame and guilt scale (Conradt et al. 2007). Body dissatisfaction will be measured with a visual analogue body dissatisfaction scale, which is sensitive to transient changes in body dissatisfaction and is strongly correlated with other established measures of state body dissatisfaction (Heinberg and Thompson 1995). Religiosity using the centrality of religiosity scale, CRS-5, which contains one question on each of the centrality of religion dimensions which are scored on a frequency scale of 1 to 5 (Huber and Huber 2012). Attitude towards a deity will be measured using the ATG-S 9 (Wood et al. 2010). Attachment to God, which has been commonly used and associated with disordered eating (Homan and Boyatzis 2010) and body image (Homan 2012), will be measured using the Attachment to God Scale (Rowatt and Kirkpatrick 2002) this is briefer than the Attachment to God Inventory (Beck and McDonald 2004). With specific reference to struggles with food and weight, religious coping will be measured using the brief RCOPE (Pargament et al. 2011). Spiritual experience will be measured using the daily spiritual experiences scale (Underwood 2011). Religious social support will be measured using the domains of congregational support and church leader support (Fiala et al. 2002) the questions will be adapted to reflect the context of this church based programme. Where possible the briefest measures have been chosen to reduce participant burden and all the scales have been amalgamated into an easy to use online survey using Bristol Online Survey platform.

Physical Activity will be measured using the short physical activity questionnaire used in the European Prospective Investigation into Cancer and Nutrition (EPIC) study (Wareham et al. 2003). Fruit and vegetable intake will be measured using the Five-a-day Community Evaluation Tool (Ashfield-Watt et al. 2007). Participant acceptability will be measured quantitatively using a questionnaire developed from the theoretical framework for acceptability of healthcare interventions (Sekhon et al. 2017). Facilitators will also be invited to consent and complete a similar acceptability questionnaire before, during and after running the programme.

4.12. Sample Size

This study will be powered to detect a clinically meaningful and statistically significant difference in emotional eating between the control and intervention at the end of the intervention months. Based on the data from the feasibility study showing emotional eating reduced by mean (SD) score of 19.4 (23.5) at 6 month follow-up. With an alpha error rate of 5% and 80% power I will need 52 participants in total for powering a trial where individuals are the unit of randomisation. Assuming an intra-class correlation coefficient of 0.206 (Thompson et al. 2012) and 10 participants recruited within a cluster I will need 15 clusters, and 150 participants in total. To optimise the effectiveness of balance using block randomisation for a 2:1 ratio, the aim will be to recruit 18 clusters in total.

4.13. Data Analysis

Baseline characteristics and follow-up data will be summarized and presented at both the cluster and individual level. Checking the effectiveness of randomization is important given blocking and the small number of clusters in the sample. Data at the cluster level will include any reported variation to programme delivery at local level (e.g., serving refreshments, time of worship or corporate prayer); although variation is not encouraged its inevitability is recognized and details of variation are collected from facilitators through their post intervention questionnaire.

The difference in the change in outcome measures between the intervention and the control group at the end of the intervention will be investigated using multi-level modelling which takes the two levels of data (the cluster and the individual) into account. Any important differences by randomisation identified between baseline characteristics will be adjusted for in the analysis at the individual level; notable differences between clusters will be adjusted for at the cluster level. Significance will be set at the 5% level, exact p values and 95% confidence intervals will be given. Analysis will be conducted on an intention to treat basis (Figure 1), with missing data input using multiple imputation.

Once the control group has received the delayed intervention, results are likely to be similar, these will be pooled so the change in outcomes between end of intervention and 2 years post-intervention are analysed as a single group cohort. Multivariate modelling will adjust for potential confounding variables.

Mediation and path analysis will be conducted to explore the relationships between the measured variables and test whether this maps onto the theoretical underpinning of the intervention. This will be approached using the structural equation modelling framework for assessing multilevel mediation as developed by Preacher et al. in 2012, the four-step approach will be used as data allows (dependent on important differences identified between clusters in the earlier stage of analysis). Step 1: Identify the mediation hypothesis to be investigated; this is based on the theroretical framework hypothesized earlier, but also takes into account observed differences between clusters which may moderate the pathway; Step 2: Ensure there is sufficient between-cluster variability to support multi-level structural equation modelling, in the absence of this group mean-centring will be considered; Step 3. Fit the within model allowing the cluster-level constructs to covary freely; Step 4: Fit the within and between models simultaneously (Preacher et al. 2010).

Rates of attendance, attrition and statistics on evaluation will be presented by intervention and control group.

5. Implication of Results

This is a protocol so results are not yet available, although recruitment has begun. Should the "Taste & See" programme prove effective it will provide strong clinical evidence of a church based group programme to improve the health and well-being of those struggling with food and weight issues in the UK.

Church based programmes like this one address health holistically, use existing social structures and a voluntary workforce that is sustainable and cost-effective, helping to alleviate the burden of obesity related diseases on the National Health Service.

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Author Contributions: Deborah Lycett conceived and designed this trial and wrote this paper.

Conflicts of Interest: Coventry University owns the copyright of the Taste & See programme. Deborah Lycett does not profit financially from the Taste & See programme.

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