

SWAT 147: Effects on retention of different weight assessment approaches during trials of Behavioural Weight Management Interventions (BWMI)

Objective of this SWAT

To evaluate the effects on retention of two weight assessment approaches (at 3 and 6 months) in the Game of Stones randomised trial.

Study area: Retention, Follow-up

Sample type: Participants, Researchers

Estimated funding level needed: Very Low

Background

Obesity is a complex condition resulting from the interplay between biological, genetic and socioeconomic factors [1,2]. Around a quarter of men in the UK are obese [3-6] putting them at risk of long-term health conditions including stroke, cardiovascular disease, type 2 diabetes and depression. One-to-one behaviour change interventions, which reduce dietary energy intake and increase physical activity are effective in weight management [7] but only a small proportion of men and in particular those from disadvantaged backgrounds, attend these types of programmes [7,8] and there is a need for research into novel ways of delivering the interventions.

Digital trials, such as those that deliver interventions by text message, can reach large numbers as well as more disadvantaged groups who are often underrepresented in face-to-face trials [9-11]. However, delivering digital-based interventions can vary significantly in terms of interaction between participants and the trial team [11]. It is uncertain how key factors (such as provider relationships and individualised support) that have been shown to enhance retention and trial outcomes in face-to-face trials [12] translate to technology-dominant trials. Furthermore, developing trusting relationships, being cognisant of the influence of stigma [13] and providing space for weight conversations [14] can help with weight-related communication and might precede actions such as advice-giving or making referrals in relation to weight. Within weight management, these appear to be important mechanisms going beyond what is delivered to how it is delivered. Links between the form of delivery, specifically interpersonal relationships, intervention effectiveness and trial retention have been found in some studies [15-18]. How best to achieve this in digital trials is unclear.

A recent feasibility 3-group randomised trial [19] allocated men to receive text messages with or without a financial incentive linked to personalised weight goals or a wait-list control and found differential retention between groups. Fewer participants in the text message plus incentive group (64%) completed the 12-months assessment compared with the text message only (79%) and wait-list groups (83%). The qualitative sub-study [20] showed the importance of the relationship between researchers and participants. Participants valued a non-judgmental, non-stigmatising approach, which appeared to interact with motivation to attend appointments for weight measurement. However, it was unclear to what extent the style of researchers and the researcher-participant relationship affected retention over the course of the trial.

Finding more effective ways to improve retention remains an important issue for trials [21]. Drop-out, and in particular differential drop-out between groups, may lead to bias. Better understanding of retention behaviour may assist effective translation of research into routine practice. However, despite increasing interest in retention in trials, the role of trial staff-participant relationships appears to have been overlooked when considering trial processes [18], especially with digitalised interventions.

Therefore, this SWAT will investigate the effect of participant-trial staff relationships on retention up to the time of the primary outcome assessment in the Game of Stones randomised trial (ISRCTN91974895).

Interventions and comparators

Intervention 1: Task-Oriented Weight Assessment: researchers conduct the weight assessment tasks at 3 and 6 months in accordance with a protocol.

Intervention 2: Relational Weight Assessment: researchers conduct the weight assessment tasks at 3 and 6 months with a focus on developing the participant-researcher relationship in accordance with a protocol.

Index Type: Method of Follow-up

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Attendance at the primary outcome weight assessment at 12 months

Secondary: Attendance at weight assessments at 6 and 24 months; participant weight stigma at 12 months; participant rating of the quality of the participant-researcher relationship after the primary outcome assessment at 12 months.

Analysis plans

The analysis population will be all available participants on an intention-to-treat basis for all outcome measures, such that randomised participants with observed data will be analysed according to the weight assessment group to which they were originally assigned.

Primary outcome:

The analysis of the primary outcome will estimate the mean difference in retention at 12 months between SWAT groups, using a linear mixed model.

Secondary outcomes:

Secondary outcome measures will be analysed similarly, using an appropriate generalised linear model, including binary logit regression for dichotomous outcomes (e.g. attendance) and ordered logit for ordinal outcomes (e.g. weight stigma).

Statistical significance will be at the 2.5% level, consistent with the assumptions made in the sample size calculation for the main Game of Stones trial.

Possible problems in implementing this SWAT

Researchers not adhering strictly to protocolised weight assessments at 3 and 6 months. Fidelity will therefore be assessed using audio-recordings of weight assessments at 3 and 6 months.

References

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Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Claire Torrens, Pat Hoddinott, Barbara Farquharson, Ronan O'Carroll and the Game of Stones Research Team

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Date of idea: 1/APR/2020

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Date of revisions: