MOTIVATE: A WEB-BASED INTERVENTION

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Impact of a web based intervention (Motivate) to increase attendance at an eating disorder service assessment appointment: a zelen randomised control trial

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Methods

Design

The research was conducted using a two arm single-consent Zelen randomised control trial.

A zelen randomised consent design (Zelen, 1979), which involves randomising participants prior to consent and then only collecting consent from those in the active condition, was proposed as the most ethical and appropriate approach for answering the research question for several reasons. Firstly people with eating disorders are often highly ambivalent about recovery (Leavey, Vallianatou, Johnson-Sabine, Rae & Gunputh, 2011), and as such adding trial consent, particularly with the knowledge that they may not receive the active condition, at a time that might be challenging for this group could be deemed unethical. The addition of full consent prior to randomisation ran the risk of resentful demoralization within the control group, potentially increasing the rate of non-attendance at assessment appointments. Hawthorne effects, which result in participants changing their behaviour as a result of knowing they are being observed may also occur (Payne & Payne, 2004). These

would not only have implications for the validity of the study, it may also pose significant risks to the health and wellbeing of the patient and their loved ones. As such the use of a Zelen design reduces biases such as those caused by resentful demoralization and Hawthorne effects. It also allowed for a trial that more closely replicates what would happen in usual clinical practice.

Recruitment

No active recruitment took place for the study. All adult referrals to the Kimmeridge Court Eating Disorders service, Dorset, UK, over the period of one year (24/10/17 - 23/10/18) were identified for potential inclusion in the study. This time period was chosen to ensure that results were not affected by seasonal variations. No power calculations were done due to limited previous literature directly relating to this research, however a post-hoc power analysis was conducted and is presented in the discussion section. Participants were referred to the eating disorder service by a health professional as part of the usual referral process. Upon referral to the service, patient information was checked by the eating disorders service staff against the following inclusion/exclusion criteria:

Inclusion criteria

1) Referrals to the eating disorders service during the study period.

Exclusion criteria

1) Inpatients or emergency and urgent cases.

2) Patients who have already been randomised into the study.

3) Non English speakers

All eligible referrals were then randomised into the study using the randomisation procedure outlined below.

Control Condition (Treatment As Usual)

Participants randomized to the control condition received standard care. This consisted of a phone call from service centre staff, with details of participants' assessment appointments, a letter, plus a compliments, comments, concerns and complaints leaflet sent to their home address.

Intervention Condition (MotivATE)

Participants randomized to the intervention condition received standard care, plus the opportunity to access MotivATE (Muir et al, 2017). MotivATE is delivered via four 15-20 minute web-based modules designed to be used prior to an assessment appointment. The content and aims of these modules is briefly outlined in table 1. Screenshots of different sections of MotivATE can be found in the supplementary materials.

Table 1: Content of MotivATE

Module	Aim	Description

1 – What happens at the first appointment?	Address expectations about the assessment appointment	Provides an interactive quiz to explore common misconceptions about assessment, information about the assessment appointment and stories and videos about others' experiences.
2 – How motivated are you?	Introduce the idea of change	Introduces people to the stages of change model with stories of others' experiences. User can choose their stage of change.
3 – Arming yourself with information	Help with recognising problematic behaviours (pre-contemplation). Address ambivalence	Information about eating disorders that relate to the pros and cons of eating disorders. Those who have selected a contemplation or preparation stage of change can complete their own pros and cons table and complete exercises designed to address ambivalence. Again, stories of others' experiences of an eating disorder are included.
4 – Preparing for your assessment	Improve confidence to attend	Includes a video of a clinician welcoming them to the assessment and allows users to make plans to attend their appointment.

Access to Motivate was offered in addition to treatment as usual via an invitation letter to access MotivATE. The MotivATE invitation letter included a brief outline of MotivATE, the

participant's ID number to be used at registration and the URL to access the intervention online.

Outcomes

Our primary outcome was attendance at initial assessment appointment. This was assessed using NHS audit data from the eating disorders service, to result in the number of DNA's (Did Not Attends) in the MotivATE group versus the control group.

Secondary outcomes were:

a) engagement with the intervention, which was examined using data on the number of sessions completed by each participant and time spent accessing them generated by the intervention.

b) Participants' perceptions of MotivATE and the perceived impact of MotivATE on their motivation to attend assessment. This was assessed using qualitative data collected from participants from the MotivATE group in semi-structured interviews. Participants in were given the opportunity to opt-in to take part in a semi-structured qualitative interview upon registering with the intervention. This triggered an automated email following the participants assessment appointment which outlined the details of the interview and invited participants to take part. At the midpoint of the study, a second follow up email, sent out two weeks after the initial invitation was also added in an attempt to improve uptake.

Due to the nature of the study design, no baseline measures or demographics were collected.

Initial Assessment Appointment

The initial assessment for both conditions was the same, constituting usual care, with attendance at this appointment being assessed using routine audit data which will be added to the secure participant database by service staff. All treatment following the initial assessment was usual care and beyond the scope of this study.

Randomisation, Allocation Concealment and Blinding

Study relevant information were placed in blank envelopes labelled with participant ID numbers. Participants were pre-randomised using block randomisation into the intervention or control arms by a member of the research team not directly involved in conducting the study (KMA). This was achieved by generating a random number string from Random.org which was then broken down into consecutive blocks of eight digits, and manually balanced to ensure even allocation in each block. The number sequence was then followed sequentially for each batch of participant invitation envelopes, which were numbered sequentially with ascending participant ID numbers, in order to assign the relevant study arm.

As participants were referred to the service they were assigned a participant ID incrementally by the service centre staff. Opaque envelopes containing the relevant information for each condition were appropriately labelled with participant numbers, allowing them to be included with the invitation to assessment letter by service staff.

Service staff maintained a single, secure record linking the participant's name to their unique participant ID. Once all participants had passed through the study, outcome data

was added to the secure record by service staff and any personal identifiers removed prior to this document being delivered to the research team.

Analysis

Initial analysis was conducted on an intention-to-treat basis with all data categorised according to the original allocation using a 2-sided 5% significance level. To examine the research question, a logistic regression was conducted. The independent variable for this analysis was the allocated condition (MotivATE/Treatment as usual); the dependent variable was attendance at assessment ('attended' and 'did not attend'). Additionally a follow up analysis was conducted to compare attendance between those who registered, or did not register, with MotivATE amongst participants within the MotivATE condition.

Usage data from the MotivATE condition was analysed using descriptive statistics in order to explore the number of participants who registered with the intervention, as well as how many of the intervention modules were accessed by users.

Qualitative data were originally to be analysed using thematic analysis (Braun & Clarke, 2006). However as a result of poor recruitment to this aspect of the study it was not possible to complete a full analysis of the data. Data were analysed as case studies instead.

Ethical Approval

The research gained HRA approval (Ref: 16/SC/0431) from the Hampshire A Ethics Committee, and was registered on Clinicaltrials.gov (Trial number: NCT02777944 (19/05/2016)) prior to commencement .