Evaluation of Pilot Online Binge Eating Disorder Group Intervention in under 18s.

Short Title: **Evaluation of Pilot Online Binge Eating Disorder Group in under 18s.**

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IRAS Number

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Research Question

Can the guided self-help protocol be delivered as an online group intervention?

Core Research Group

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Stakeholders

The following stakeholder groups have been identified:

- RISE Eating Disorder service users (current) who are diagnosed with a Binge Eating Disorder
- RISE Clinicians (including Psychologists, Cognitive Behavioural Therapy Therapists, Dieticians, and Assistant Psychologists)
- Non-client-facing service providers such as Service Managers and Commissioners/members of Clinical Commissioning Groups

Funding

This piece of research is being supported by the RISE Eating Disorder service at Coventry & Warwickshire Partnership NHS Trust and is not externally funded.

Sponsor

Coventry Warwickshire Partnership NHS Trust

Timeline

Start Date: 1st February 2023 Duration: 6 months

Background and Rationale

The National Institute for Health and Care Excellence (NICE) Guidelines (2017) recommend cognitive behavioural therapy (CBT) group therapy as an intervention for Binge Eating Disorders (BEDs). These guidelines do not differentiate between what is offered to adults and what is offered to under 18s for BED. Downey (2014) identified that there is limited research on group interventions for Binge Eating Disorder. Further, BED was only established as a diagnosis in the Diagnostic and Statistical Manual of Mental Disorders 5th Edition (American Psychiatric Association, 2013; DSM-5), which means that research is still in the early stages (Kober & Boswell, 2017).

Malhotra & Baker (2019) highlight that group therapy is an effective method of treatment for a variety of psychiatric and behavioural disorders. They found that it affects patients positively through the Yalom Therapeutic Factors (Yalom & Leszcz, 2020). For example, patients realising that there are others similar to them, improving their self-concept by assisting others and witnessing the success of other group members allows them to envision themselves also succeeding have all been shown to be beneficial. Rørtveit et al. (2021) found that a group program was thought to be an essential part of treatment. Jones (2019) also found that a CBT group intervention showed improvements for the participants and helped them regain control of their eating. Yu et al (2021) compared an online BEG group intervention to a face-to-face group amongst adults and found that the online option was feasible and effective. These studies were undertaken within the adult BED population and no paper was found evaluating the effectiveness or feasibility of a group intervention for under 18s.

Within RISE Eating Disorders Service, based in Coventry and Warwickshire Partnership NHS Trust (CWPT) individuals diagnosed with BED are offered guided CBT self-help based on the book Overcoming Binge Eating by Christopher Fairburn (2013). Due to the growing evidence that group therapy can be beneficial for adults with BED, we aim to explore whether or not this is also effective in under 18s. The large geographical area that the CWPT RISE service covers led us to developing the intervention for online use with the aim of increasing attendance and continued participation. The protocol for this BED group intervention has been developed using the current format for individual interventions based on Christopher Fairburn's book as a guide. The benefits of the research are that people on a waiting list will be offered treatment earlier.

Aims

The aim of our study is to assess whether the group intervention can be delivered per the protocol and obtain feedback from the participants of any recommended amendments/adaptations.

Methods

This research will:

1. Review individuals on the RISE Eating Disorder treatment waiting list for Binge Eating Disorder to assess their suitability for an online group intervention. Individuals will be reviewed in order on the waiting list.
2. A carer information session will be held online to discuss their role throughout the research.
3. An online one hour group intervention will be delivered once a week for 10 weeks.
4. Follow-up questionnaires will be distributed to carers 1 month after completion of group.

<u>Participants</u>

Individuals on the RISE Eating Disorders Treatment Waiting List will be reviewed by the RISE clinicians who will be facilitating the group intervention for suitability.

Inclusion criteria

- Diagnosed with Binge Eating Disorder
- Under 18 prior to the group starting
- Speaks English

Exclusion criteria

- If underweight
- If have a serious physical illness
- If pregnant
- Physical Health problems due to eating problem
- If mental health needs to be stabilised
- If significant problem with alcohol, drugs, or repeated self-harm
- Not in a place to start (changes upcoming or ongoing)

Procedure

Individuals from the treatment waiting list meeting the inclusion criteria will be approached by CWPT RISE study team clinicians to ask if they are interested in taking part in the research study. Those who express and interest will be offered a face-to-face review appointment with two clinicians, including the chief investigator. If, from the review, it is felt that it is appropriate to offer them the study group intervention, it will be explained to them in detail and they will be handed a Patient Information Sheet (PIS), one for themselves and one for their parent / carer. They will be given a week to decide whether or not they would like to take part in the study after which time a clinician will contact them via telephone to ask them what they have decided and to answer any questions. The chief investigator will ensure that the individual is truly interested in the approach and that there is no coercion. Consent forms will be sent via email, which they will be asked to send back signed electronically and send back via email. Once the individual and their parents/carers have signed the consent forms, the parent /carer will be invited to attend an introductory information session online. This session will explain the principles of the group and how they can support the young person throughout the course of the group. Baseline questionnaires will be completed pre-intervention.

Group intervention

The BEG intervention protocol is a separate attached document. The outline of the group consists of:

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Upon completion of the group, the participants will be asked to complete the questionnaires again.

Participants will undertake a follow-up appointment face-to-face or online at one month post research intervention to complete the questionnaires again and to assess whether or not they continue to require RISE Eating Disorder Service support. If further support is required from the RISE Eating Disorders service, this be will offered by the team. If a need is identified for support that is not offered by the RISE Eating Disorder service, they will be signposted and/or referred to the appropriate service. If they no longer require treatment and are able to manage their binges, they will then be discharged for the service.

Measures

Questionnaires will be completed at baseline (pre-intervention), at completion of group and at one month post-intervention. Individuals will also be provided with an online feedback form at the end of the last group session to complete anonymously to assess their experience of the group.

The questionnaires used are: Eating Disorder Examination – Questionnaire (EDE-Q), Revised Children's Anxiety and Depression Scale (RCADS) Child and RCADS Parent. These are the standard questionnaires used within the service to monitor eating behaviours and mood. The EDE-Q was chosen over a specific binge eating one as this allows to monitor if the eating behaviours change to a different type of eating behaviour as it measures restriction and binging.

The results will be analysed quantitively with repeated measures statistical tests. We are looking for the EDE-Q scores to reduce which would suggest a reduction in symptoms. Furthermore, we are monitoring mood through the RCADS to see if there is any change in their mood following the treatment.

The feedback form will be utilised qualitatively via content analysis to highlight any changes that the participants would suggest to the group and the space to express verbally how they experienced the group.

Anticipated impact and dissemination

If effective, the group intervention will be offered as a treatment option to service users from the RISE Eating Disorder Service going forward. The results will be disseminated through scientific papers and conferences. If the intervention is successful it might encourage services from other organisations to adopt this approach.

Ethics/regulatory approvals

Declaration of Helsinki

The Chief Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

Guidelines for Good Clinical Practice

The Chief Investigator will ensure that this study is conducted in full conformity with relevant regulations and with the ICH Guidelines for Good Clinical Practice (CPMP/ICH/135/95) July 1996.

Approvals

The research protocol, intervention protocol, informed consent forms, and participant / carer information sheets will be submitted to the Health Research Authority (HRA) and the CWPT R&D office for local approval.

The Chief Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

Data monitoring

The study may be monitored or audited for compliance with the Department of Health Research Governance Framework for Health and Social Care 2005.

Patient confidentiality

Study participants will be assigned a unique study identifier on recruitment. All data collected thereafter will be assigned to this study identifier. The study staff will ensure that the participants' anonymity is maintained. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act.

Ethical Considerations

Protecting patients' dignity is a critical part of this study. Study procedures, data handling and storage have been scrutinized to ensure that any privacy issues are mitigated.

All data will be kept strictly confidential.

Patient and Public Involvement

Service user involvement was sought. Feedback was positive in regards to the group and structure and recommendations have been taken into consideration.

End of study

End of study will be when all data has been collected, analysed and an end of study report produced.

Long term storage

All data will be kept electronically password protected. Only person who has access is the Chief Investigator. This will be archived for 5 years and destroyed following this.

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