Participant Information Leaflet

Study Title: Workplace-based brief CBT (CBT-T) for Eating Disorders

Investigator(s): Professor Glenn Waller (University of Sheffield), Professor Caroline Meyer (University of Warwick, Professor Guy Daley (Coventry University), Sean Russell (WMCA), Dr Lukasz Walasek (University of Warwick), Dr Carla Toro (University of Warwick), Dr Krishane Patel (University of Warwick), Dr Talar Moukhtarian (University of Warwick), Tabitha Jackson (University of Warwick), Agatha Payne (University of Warwick).

Introduction

You are invited to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish and take time to decide whether you would like to take part.

If you have any questions or would like more information, please contact Dr Carla Toro wmg-bite@warwick.ac.uk or Prof Glenn Waller g.waller@sheffield.ac.uk.

Who is organising and funding the study?

The design, implementation and management of this study is being conducted by the University of Warwick, and is funded by Midlands Engine.

What is the study about?

Cognitive-behavioural therapy (CBT) is a psychotherapeutic approach to eating disorders that has been well researched. There are different forms of effective CBT for eating disorders, which are similar in lots of ways. One specific form of CBT, known as CBT-T (where the 'T' stands for 'ten sessions'), is a time-limited, focused therapy, which is ten sessions long (followed by two follow-up sessions). It starts by addressing your safety, then aims to help you change your eating, your beliefs about food, and your body image. It may also help you to reduce any anxiety and other emotional concerns.

The evidence shows that CBT-T is suitable for adults who have eating disorders other than anorexia nervosa. Research has shown that CBT-T can be effective for women and men who are at a near-healthy weight or above, in healthcare settings.

The aim of this study is to determine whether CBT-T can be delivered effectively in a non-health service setting: for employees within the workplace. We are interested to know how many employees sign up and whether the therapy is helpful in the workplace. The study is open to full-time and part-time permanent employees, apprentices, and those on fixed-term,

temporary or honorary contracts.

What would taking part involve?

If you decide to take part, we will contact you to ask you to fill in some further questionnaires and to arrange you first therapy appointment. We will also notify your GP of your involvement in the trial *(please note, if you are currently pregnant we may also notify your midwife). Y*ou will be asked to attend up to 10x 45–60-minute weekly therapy sessions, and 2 follow-up appointments at 1 and 3 months after the 10th session. These will be delivered via specially trained therapists over Microsoft Teams during office hours. There will be weekly shorter questionnaires to complete throughout the intervention. Between therapy sessions, you will be asked to complete tasks as part of the intervention. At the end of the study, you may be invited to take part in a feedback survey.

On some occasions, online therapy sessions will be video recorded for training purposes by the lead researcher. You will be asked to consent to this and be notified at the start of the session.

Throughout the intervention we will be asking you questions about your safety. If we become concerned about your wellbeing at any point we will contact your GP, however, we will notify you before doing so.

The following page contains a consent form, which must be completed if you would like to take part in the study. Participation is completely voluntary and choosing not to take part will not affect you or your employment in any way. You can also choose to withdraw your participation without giving a reason at any time. Further details about withdrawing from the study are provided later on in this document.

What are the possible benefits of taking part in this study?

CBT-T is much shorter (10 sessions) than the standard CBT for eating disorders (20+ sessions) and has been shown to be equally as effective in healthcare settings. It may also help you to reduce any anxiety and other emotional concerns. Whilst we cannot guarantee that you will recover, if you engage fully with CBT-T then you have a stronger chance of a full recovery and being able to get on with your life.

There will be no reimbursement for participation in this study.

What are the possible disadvantages, side effects or risks, of taking part in this study?

As with all therapy, you may experience some discomfort when talking about your experiences. You may also experience a natural increase in anxiety when trying out new behaviour patterns. You will be fully supported by your therapist throughout this time and can share any concerns with them.

Will my taking part be kept confidential?

Your data will be kept confidential throughout the study. All study data will be collected in electronic format through online surveys and via therapy sessions. Research data will be de-identified as quickly as possible after data collection and you will be assigned a unique

participant ID number. We are collecting your phone number and email address to contact you during the study (e.g. to arrange therapy sessions). Personally identifiable data (e.g. name, email, phone number) collected in this study will be stored in password protected files, kept separate from study data; all of which will be stored securely on the University of Warwick servers.

Your participation and individual data collected from the study will not be shared with your employer, nor are you under obligation to report your participation to your employer. Participating businesses may receive a summary report which will not include any identifiable information about enrolled employees. Additionally, no identifiable information (e.g., name) will be used for analysis or in publications emerging from this study.

The only time we may need to breach confidentiality is if we have a concern about your safety, but we will always notify you that we are doing this. In these instances, we may need to contact your GP or call 999 in an emergency.

What will happen to the data collected about me?

Research data will be pseudonymised as quickly as possible after data collection. This means all direct and indirect identifiers will be removed from the research data and will be replaced with a participant number.

As a publicly-funded organisation, the University of Warwick have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, such as this, we will use your data in the ways needed to conduct and analyse the research study. We are committed to protecting the rights of individuals in line with general data protection regulations. The University of Warwick will keep identifiable information about you for 10 years after the study has finished.

Data Sharing

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. The University of Warwick has in place policies and procedures to keep your data safe.

This data may also be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project.

For further information, please refer to the University of Warwick Research Privacy Notice which is available here:
https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice or by contacting the Legal and Compliance Team at GDPR@warwick.ac.uk.

What will happen if I don't want to carry on being part of the study?

Participation is entirely voluntary; you have the right to withdraw at any time without giving a reason and this will not affect you or your employment in any way. If you wish to withdraw, you will need to email the research team wmg-mhpp@warwick.ac.uk stating your intention to withdraw. Please note that it will not be possible to withdraw your data retrospectively after June 2022, at which point the data will have been anonymised. To safeguard your rights, we will use the minimum personally-identifiable information possible and keep the data secure in line with the University's Information and Data Compliance policies.

What will happen to the results of the study?

The data collected will be analysed by researchers at the University of Warwick. The results are expected to be published in scientific journals and reported at national and international research meetings. Additionally, summary reports will be shared with all participating employers and our funders, the Midlands Engine. It will not be possible to identify you personally in these publications and reports.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the University of Warwick's Biomedical & Scientific Research Ethics Committee (BSREC 152/20-21).

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance

Research & Impact Services
University House
University of Warwick
Coventry
CV4 8UW
Email: researchgovernance@warwick.ac.uk
Tel: 02476 575733

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter: DPO@warwick.ac.uk.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Thank you for taking the time to read this Participant Information Leaflet