General Practitioner Information Sheet
REEACT: Computerised CBT for Depression
(ISRCTN 91947481)

Background

Cognitive behaviour therapy (CBT) has emerged as the leading evidence-supported form of brief psychotherapy for people with depression. However, it is unfeasible that demand for CBT can be met from existing therapist resources. Primary care doctors therefore have relatively few treatment options other than antidepressant medication or referral to specialist psychology services where long waiting lists are likely.

Computerised CBT represents an alternative form of therapy delivery that has the potential to enhance access to psychological therapy. Various packages are available, some of which are commercial products and others are free-to-use. However we do not know how much more clinically and cost effective computerised CBT is, compared to usual care alone. We also do not know whether the additional cost of the commercial packages compared with the free-to-use versions is justified.

Research Aims

This will be a fully randomised trial of usual GP care for depression versus the addition of one of two computerised CBT packages to usual GP care. We will include a concurrent economic and qualitative evaluation to meet the following specific aims:

1. To establish the clinical and cost effectiveness of the addition of computerised CBT to usual GP care over a two year follow-up period.
2. To establish the acceptability (to patients and clinicians) of computerised CBT.
3. To establish the differential clinical and cost effectiveness of a free-to-use computerised package, in comparison to a commercial pay-to-use computerised CBT package over a two year and longer-term time horizon.

We plan to randomise **690** participants with depression, recruited in primary care, to either usual GP care, *Beating the Blues* plus usual GP care or *MoodGYM* plus usual GP care. Clinical outcome will be measured at 4, 12 and 24 months. Recruitment will occur over two years.

What we ask of you

We would like each study GP to recruit at least 10 patients into the trial over the two-year recruitment period. Ideally we would like each GP to recruit a patient a month. To do this, we ask you to identify patients who present with depression. This can be done by screening the practice records for patients with depression, according to a

protocol. When potential participants are identified, we will supply you with recruitment packs to post directly to them. If interested in participating, the patient will be advised to contact the research team directly.

You can also refer patients directly. We would like you to establish whether the patient would consider taking part in the trial and to obtain consent from them to be contacted by us. We ask that you then fax a pre-printed 'Permission for Release of Personal Details' form and a referral form to us. We will then contact the patient directly so that we can explain the trial and arrange an appointment to see them. We also have an information sheet and invitation letter for you to give them at that consultation. All study documentation will be stored in an easy to use study folder. Practice-attached nurses and members of the Primary Care Mental Health Team can also refer into the study.

However the patient has been recruited, if the patient is eligible and consents to participate, we will immediately randomise them and inform them of their treatment allocation. If allocated to usual care alone, we will inform you and advise them to continue with their GP care, as planned. If allocated to either of the two computerised CBT packages, we will make arrangements to initiate this treatment and inform you. If the patient is not eligible we will inform you and advise them to continue with their GP care as planned. Whatever the outcome we will also inform you of the patient's PHQ9 score.

- The study is not 'blinded' so both you and the patient would know which treatment group they had been allocated to. You would continue to have overall clinical responsibility for your patient and provide your normal follow-up. We only ask that you inform us if the patient is withdrawn for whatever reason and notify us if you identify any Serious Adverse Events. We will provide a form for reporting these events.
- We will follow the patient up at 4, 12 and 24 months after randomisation. This can be done by interview (either face-to-face, or over the phone), or by postal questionnaires, depending on patient preference.
- We will also need access to the medical records of participants to determine NHS resource use and whether any medication has been prescribed. We would do so at a time that is convenient to you and the practice team.
- Depending on how recruitment is progressing we may approach you to ask about screening for potential participants in the waiting room. All potential participants will, of course, be seen by yourself for an assessment before being referred to the trial.

Financial arrangements are in place to ensure that any time you or your practice staff spend in recruiting patients to the trial are reimbursed.

Please do not hesitate to contact <*insert local investigator and researcher details*> if you have any questions or queries.

Thank you for considering taking part in this research.