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Comparing counseling alone versus counseling supplemented with a well-being mobile phone app for university students with anxiety or depression

Submission date
16/06/2016

Recruitment status
No longer recruiting

Registration date
20/06/2016

Overall study status
Completed

Last Edited
19/08/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
There is a lack of research about student counselling in the UK and a new movement is encouraging services to be more research active. In recent years, the demand on student counselling has increased and services are seeing more students with symptoms of anxiety and /or depression. There has also been a recent surge in smartphone applications (apps) offering tools to improve well-being, which provides a unique opportunity to complement counselling. However, with a very large amount of apps on the market, it is difficult to decide which features are appropriate or beneficial. The aim of this study is to find out whether a wellbeing mobile phone app can be incorporated with face-to-face counselling in a university counselling service seeing students with symptoms of anxiety or depression.

Who can participate?
Students at the University of Sheffield who are showing signs of anxiety or depression and have been approved for counselling.

What does the study involve?
All participants receive up to six sessions of counselling in line with standard practice and will not be disadvantaged for taking part. The number and frequency of sessions will be determined through discussions between participant and their therapist. Eligible participants are allocated to one or two conditions based on the judgement of their therapist after their initial assessment. Those in the first group receive the face-to-face counselling sessions alone. Those in the second group receive the counselling, supplemented with guided use of a wellbeing app between and within sessions. Therapists discuss various app features with participants during the counselling sessions which may include using a tablet to access exercises, and encourage them to use specific app features between counselling sessions and review their activity in preparation for the next counselling session. Usage of the app is catered to participants' individual needs and is reviewed at each counselling session. The face-to-face counselling sessions in this condition are recorded in order to show how the participant/therapist discuss

various app features (sessions in the other condition are not recorded). The app itself offers daily tools for coping with stress, anxiety and low mood, based on cognitive behavioural therapy (a type of therapy designed to change the way a person behaves), meditation and mindfulness (awareness of the present moment and self). At the start of the study and then again after three and six months, participants in both groups complete a range of questionnaires to assess their mental wellbeing. Therapists are also invited to focus groups in order to provide their feedback about the treatment approach.

What are the possible benefits and risks of participating?
Participants benefit from receiving face-to-face therapy with a wellbeing app which is not available outside of this study. Participants will be assisting development of their university counselling service. In addition, the audio recording of counselling sessions ensures that all standards are met within counselling. Participants will also receive a £10 shopping voucher at 3-months and again at 6-months to acknowledge their time spent completing additional research measures. Shopping vouchers will be provided irrespective of whether participants complete the measures. There is a small risk that participants may find completing questionnaires to be boring, or that they may not find the features of the app to be useful.

Where is the study run from?
University of Sheffield student counselling and well-being service (UK)

When is the study starting and how long is it expected to run for?
February 2016 to February 2017

Who is funding the study?
British Association for Counselling and Psychotherapy (UK)

Who is the main contact?
1. Ms Emma Broglia (public)
e.l.broglia@sheffield.ac.uk
2. Professor Michael Barkham (scientific)
m.barkham@sheffield.ac.uk
3. Dr Abigail Millings (scientific)
a.millings@sheffield.ac.uk

Contact information

Type(s)
Public

Contact name
Miss Emma Broglia

ORCID ID
http://orcid.org/0000-0003-2137-8187

Contact details
University of Sheffield
Department of Psychology
Western Bank
Sheffield

United Kingdom
S10 2TP
+44 (0)114 222 1202
e.l.broglia@sheffield.ac.uk

Type(s)
Scientific

Contact name
Prof Michael Barkham

Contact details
Clinical psychology department
University of Sheffield
Western Bank
Sheffield
United Kingdom
S10 2TP
+44 114 222 6527
m.barkham@sheffield.ac.uk

Type(s)
Scientific

Contact name
Dr Abigail Millings

ORCID ID
http://orcid.org/0000-0002-7849-6048

Contact details
Psychology department
University of Sheffield
Western Bank
Sheffield
United Kingdom
S10 2TP
+44 114 222 6525
a.millings@sheffield.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
006171

Study information

Scientific Title
Counseling plus Apps for Students Experiencing Levels Of Anxiety or Depression (CASELOAD): A feasibility trial

Acronym
CASELOAD

Study objectives
The aim of this study is to explore whether combining face-to-face counselling with a well-being mobile phone app is an acceptable, feasible and potentially helpful treatment option for university students experiencing symptoms of anxiety or depression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of Sheffield Psychology Research Ethics Committee, 05/01/2016, ref: 006171

Study design
Non-randomized feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please request participant information booklet and/or clinician information booklet from the contact details provided.

Health condition(s) or problem(s) studied
Mental health

Interventions
Participants are allocated to a condition based on clinical judgment of a therapist who provides the initial clinical assessment. The decision is based on the therapists' judgment on the client's appropriateness for the intervention (supplementing counselling with guided use of a well-being app). Information on this decision process will be used to produce guidelines to aid clinical judgement on clients' appropriateness for the intervention being tested. Treatment preference and acceptability of randomization will be recorded from participants and therapists, when entering the trial.

Face-to-face therapy supplemented with guided use of a well-being app (intervention):
Up to six sessions of face-to-face counselling will be offered to participants in line with standard practice at the UCS. Sessions will be 50-minutes in length and the frequency of sessions will be determined through counsellor-client discussions. As well as the standard level of care, counselling sessions will be supplemented with guided use of a behavioral tracking well-being app to promote engagement within and between face-to-face sessions. Clients and therapists will have the opportunity to use the app on a tablet during counselling sessions to facilitate discussion and to aid the decision process for setting goals and reviewing client progress. Through these discussions, clients will be guided through various app features to decide on which activities would be beneficial to use between face-to-face sessions. App features may include:
1. Behavior tracking: mood, thoughts, sleep, relationships, time outside, alcohol, exercise, medication, hygiene, eating quality
2. Reflective thinking: guided CBT, mindfulness and positive visualization exercises
3. Guided relaxation: breathing, meditation and body scanning exercises
4. Peer led support: through participation with anonymous online communities and private groups.
Clients will be randomly prompted to engage with the app daily and to log various behaviors. Clients will also be encouraged to prepare for their counselling sessions by reflecting on their diary entries and deciding on what they would like to address in the session. During face-to-face sessions, therapists will be encouraged to review client's app activity, discuss the client's reflections and progressively adjust goals where appropriate. Therapists will be provided with a tablet to use with clients in sessions which may include clients accessing their app account to display their logged activities with their therapist. Sessions will also be audio-recorded with the tablet to be more discrete than traditional recording equipment. Audio recordings will be analysed to explore how various app features are discussed during counselling sessions. For this reason, audio recording will be specific to the intervention condition and clients in the control condition will not be audio recorded.

Treatment as usual/TAU (control):
Up to six sessions of face-to-face counselling will be offered to participants in line with standard practice at the University Counselling Service (UCS). Sessions will be 50-minutes in length and the frequency of sessions will be determined through counsellor-client discussions. If participants are shown to require more than six sessions, treatment will continue outside of the trial and will be supported by the counselling center. On this occasion, trial data will only be collected up to session six. Therapists are accredited with the British Association for Counselling and Psychotherapy (BACP) and will be provided with the most recent version of BACP's competency framework. Therapists will also be asked to describe their model of practice and specific therapeutic style to enrich understanding of the service's standard of practice.

A range of clinical measures will be used at baseline (pre-treatment), 3-months and 6-months after joining the trial. Measures will be used to monitor changes in: depression (PHQ9), anxiety (GAD7), psychological functioning (CORE-10), student-specific issues such as academic distress /substance misuse/family distress/eating concerns/hostility (CCAPS), and resilience (CD-10). The strength of the therapeutic relationship will be measured at session 3 of counselling (WAI), and client service satisfaction will be measured at the last counselling session (CSQ8). Clients' experiences of using the app with therapy will be explored with follow-up telephone interviews and therapist experiences will be explored with a focus group at the end of the study.

Intervention Type
Behavioural

Primary outcome measure
Feasibility of the intervention is assessed through analysis of therapy recordings, interviews with clients and focus groups with therapists throughout the study.

Secondary outcome measures
Clinical measures (baseline, 3 and 6-months):
1. Depression is measured using the Patient Health Questionnaire (PHQ 9)
2. Anxiety is measured using the Generalized Anxiety Disorder questionnaire (GAD 7)
3. Psychological functioning is measured using the Clinical Outcomes in Routine Evaluation (CORE-10)
4. Context-specific symptoms are measured using the Counselling Center Assessment for Psychological Symptoms (CCAPS)
5. Resilience is measured using the Connor-Davidson resilience scale (CD-10)

Therapeutic measures (therapy session 3 and end):
1. Strength of the therapeutic relationship is measured using the Working Alliance Inventory-Short (WAI-12)

Service impact (last therapy session):
1. Client Satisfaction Questionnaire (CSQ-8)
2. Interviews with participants

Academic measures (end of therapy):
1. Academic distress is measured with the Counseling Center Assessment of Psychological Symptoms (CCAPS; subscales: academic distress, family distress, substance abuse, eating concerns, hostility, social anxiety, anxiety, depression) which is administered at the start of every therapy session
2. Academic coping is measured via one-to-one interviews with participants who have finished therapy to explore how they feel counselling may have influenced their university experience and ability to cope academically

Usage and acceptability of well-being app:
1. Way in which clients/therapists discuss app activities and app features is assessed through reviewing therapy recordings
2. Therapist experiences of combining the app with therapy are measured through focus groups conducted at the study end
3. Usage overtime is assessed through analysis of app data

Overall study start date
01/02/2016

Completion date
28/02/2017

Eligibility

Key inclusion criteria
1. Registered student at the University of Sheffield
2. Approved for counselling (based on therapist assessment at triage)
3. Meet clinical cut-off for anxiety (10 on PHQ-9) or depression (10 on GAD-7)

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
Planned sample size: 40; 20 intervention : 20 control

Total final enrolment
38

Key exclusion criteria
1. Present high risk to self or others (determined by therapist assessment at triage)
2. Currently receiving therapeutic support

Date of first enrolment
15/02/2016

Date of final enrolment
30/10/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Sheffield Student Counselling and Wellbeing Service
36 Wilkinson Street
Sheffield
United Kingdom
S10 2GB

Sponsor information

Organisation
University of Sheffield

Sponsor details

Western Bank
Sheffield
England
United Kingdom
S10 2TN
+44 (0)114 222 2000
psychology@sheffield.ac.uk

Sponsor type
University/education

Website
http://www.sheffield.ac.uk/

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Research organisation

Funder Name
British Association for Counselling and Psychotherapy

Results and Publications

Publication and dissemination plan
1. Findings will be disseminated in professional clinical journals and peer-reviewed academic journals
2. Findings will be presented at academic conferences and as potential training workshops for university counseling services
3. All participants will receive a summary of findings which will be made available electronically and promoted on the UCS website

Intention to publish date
28/02/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/01/2017		Yes	No
Results article	results	15/08/2019	19/08/2019	Yes	No