Developing **E**-health **S**ervices (DES): The feasibility and acceptability of group based video-conferencing for adults with depression

Brief Protocol

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Version 3

Trial Number: NCT03288506

Introduction

Depression impacts 1 in 5 people in the United Kingdom and is a significant risk factor for self-harming behaviours and suicide. Research has shown that those experiencing depression may feel embarrassed about seeking help from a health professional and ultimately decide not to seek support at all. This project seeks to give those people an alternative option to face-to-face support by developing a new online service using video conferencing technology. This technology has shown to be beneficial in treating a number of mental health problems. However, as no widely available services of this type exist in the UK we do not know the full extent of potential benefits. The project seeks to answer the following questions: (1) what is the likely interest in video conferencing services for depression? (2) Which groups of people are likely to use the service? (3) How much will this service cost? (4) How much change is likely to occur when receiving therapy via video conferencing? Results will be compared from groups that receive the video-conferencing service and those on a waiting list for the service. Participants in both groups will be asked to complete surveys and take part in interviews before and after the therapy takes place.

Participants will be adults seeking support for depression (aged 18+), residing in Northern Ireland who are able to give informed consent and who have not previously accessed services by AWARE NI in the past year. Depression does not discriminate across socio-economic backgrounds, culture or ethnicity and thus this project with be of benefit to a wide range of individuals. It is hoped this project will inform best practice guidelines that will be helpful to other organisations. Groups are not suitable for those experiencing strong suicidal feelings (these individuals will be signposted to other services e.g. G.P and Lifeline).

Methods

Aware NI have been delivering peer led support group interventions since 1996. They are the largest (non-statutory) provider of depression services in Northern Ireland. The current group intervention training offered by AWARE is OCN Accredited and is available across 24 registered sites throughout Northern Ireland. In 2013, the service was independently evaluated (Collins, 2013). As part of the early development of this project, the PI has attended several support group sessions to speak to current service users in order to gain some insight into the practical issues involved as well as gain a more in-depth understanding of the various intervention components. The focus of the feasibility study will be on transferring this pre-existing and established intervention into an online format. The study will follow the Medical Research Council guidelines (Craig et al, 2008) for developing complex interventions by assessing the feasibility of a large scale Randomised Controlled Trial to test the effectiveness of conducting a peer led support group intervention for depression in adults using VC technology.

The study will have two main phases:

Phase 1: The development and in-house testing of an intervention protocol tailored towards Video Conferencing (VC) based delivery of current face-to-face peer support services. This will include interviews with facilitators, staff and current AWARE NI service users and observations of face to face groups. (Mar - May 2017)

Phase 2: Delivery of an 8-week group based VC support service for adults with depression. A between groups design comparing the intervention group and a waiting list control group will be used. Outcome measures (described below) will be recorded at baseline, week eight and six months using validated measures. Qualitative data in the form of interviews and fieldwork observations will also be gathered during this 8-week period. (Jun - Sept 2017)

Phase 1: Intervention development, training and in-house testing (Mar - Apr 2017)

During Phase 1, focus groups and interviews will be conducted with current service users to explore issues, such as the benefits of a VC support service, the barriers to accessing such a service and any suggestions regarding its current development. Member(s) of the research team at QUB will also observe face to face support groups (see Appendix D). This process is known as 'modelling' whereby the researchers use qualitative techniques to develop an understanding of the intervention and its possible effects (MRC, 2008: 4). This ensures that the intervention incorporates the needs of both AWARE NI as well as service users.

In house testing will be conducted with AWARE NI staff to identify and address practical issues for example in using equipment (for example setting up cameras/speakers), logging in to the video conferencing site (Google Hangouts) as hosts and instructions needed to support staff. QUB researchers will observe staff and facilitators using the technology and interviews with staff and facilitators after testing. Following in-house testing, a short training programme will be developed and delivered to test the equipment and allow the AWARE NI facilitators to become familiar with the technology. Ray Lawlor, Digital Director at Elm House Creative, will provide support with development of the online service and training.

Subsequently, a protocol will be produced for facilitators to complement the training programme. The manual is expected to include guidance around practical issues e.g. logging in as facilitators; checks that should be made at the start of each session (such as internet connection); alerting members as to when sessions will be beginning; checking sound issues; and informing the group if a member of the research team is observing the VC session. Guidance will also relate to dealing with drop outs and maintaining attendance records. Important ethical considerations including confidentiality and participants who become distressed will also be addressed in this manual and training. Current protocols from AWARE NI's face-to-face groups will be integrated into the manual and adapted as appropriate for VC groups.

Current service users, staff and facilitators will be recruited through a convenience sampling method. Participant Information Sheets and Consent forms will be provided to group members through their group facilitators (see Appendix B, C, G and H). Potential participants will be informed that AWARE NI are developing a new online support group service and will be invited to take part in the development of this service by sharing their ideas and allowing staff from QUB to observe their face to face group. Signed consent forms will be gathered at the support group meetings attended by QUB. This may also involve demonstrations of the new technology. Qualitative data gathered at this stage will be used to refine the intervention and its operation.

Preliminary discussions have already taken place between AWARE NI, QUB and Ray Lawlor around development ideas such as promoting the service, registration processes, security and development of a user dashboard for group members. Groups will be hosted securely through Google Hangouts and any information exchanged stored on an encrypted server.

Phase 2: Intervention delivery and evaluation (May to October 2017)

Approximately 4 - 6 VC groups (6-8 participants per group) will be delivered on a weekly basis for eight weeks. Groups will be facilitated peer facilitators from AWARE NI who are trained and experienced in delivering face to face support groups. Groups will be hosted securely through Google Hangouts. The online group will mirror the structure and format of face-to-face groups. Evaluation of groups will involve collection of outcome measures using validated instruments, interviews with group members/facilitators and observations of groups (described below).

Recruitment

Advice was taken from the research team's statistician (Dr Chris Cardwell) and the Northern Ireland Clinical Trials Unit on sample sizes required for the feasibility study. As such, a total of 100 participants will be sought for this study.

Online support groups will be advertised as a new service by AWARE on the home page of the organisations website. Invitation to participate will be through an introductory page (see Appendix F). The advertisement will specify that AWARE NI are expanding their services to include a new online support group service and that QUB will be working with AWARE NI to evaluate this new service. If participants are interested in the service and in taking part in the evaluation, they will be invited to click on a link that will lead to further information (the Participant Information Sheet). Consent will be obtained online in the first instance as a necessary step in registration and reaffirmed verbally during the VC sessions. Inclusion criteria will be that participants are 18 years or older, not currently an AWARE NI service user or accessed AWARE NI services in the past 12 months, a resident of Northern Ireland and not actively suicidal.

Registration will close once the target of 100 registers persons has been reached. Those who attempt to register after this will be advised that capacity has been reached and that they can add their name and contact details to a waiting list to be informed of when the service will become available again. This will include basic information only e.g. first name, email, age and gender. These individuals will also offered face to face support by AWARE NI outside of the study. The number of persons registering interest overall will be recorded as a measure of demand for the service and will inform the recruitment strategy of the larger RCT study.

The registration process will involve completion of several baseline measures including demographic information (first name, date of birth/age, gender, postcode, and information on any services currently receiving or accessed within the last year) and completion of validated measures of health status (see appendix A).

Randomisation

Randomisation will take place following registration and completion of baseline measures (see section below). Each participant will be assigned a unique individual number and a simple random sampling procedure will be performed using online software available at http://www.randomization.com. This will result in approximately 40 participants being invited to join the VC intervention. The decision on this number was based on organisational capacity to deliver VC groups concurrently. The remaining registered participants will act as a waiting list control group (to be offered the intervention at the end of the study).

Data collection

Outcome measures will be recorded at baseline, week eight and six months. The research team will explore the appropriateness of the following validated instruments; Patient Health Questionnaire (PHQ-9), EQ-5D-5L measures of health outcomes and an adapted version of the Client Service Receipt Inventory (CSRI) for economic appraisal. Completion of questionnaires at each stage is expected to take approximately 5-10 minutes in total. These measurements have shown previous validity and reliability in similar studies (Gilbody et al, 2007; Chong and Moreno, 2012). Feasibility will be assessed using depression outcomes; ability to recruit and retain; and fidelity (i.e. consistency of implementation across groups). Acceptability will be assessed by comparing attendance across

groups, dropout rates and using through the qualitative methods (interviews and observations) specified to explore (1) reasons for taking part; and (2) user satisfaction.

Baseline - The registration process will involve completion of several baseline measures including demographic information (first name, date of birth/age, sex, postcode, email address and information on any services currently receiving or accessed within the last year) and completion of validated measures of health status (appendix A). Data will also be collected regarding the device they plan to use to log in to the support group (e.g. phone, PC, IPad etc.).

Evaluation point 1 - At the end of the 8 week intervention period, the survey will be re-administered to participants within both the intervention and control groups. Survey data will also be gathered on use of other services since registration. An optional comments box will be included for collection of qualitative data. In addition, a series of semi-structured qualitative interviews with intervention group participants will be completed (n= 5 - 8). These will be conducted online and explore issues around acceptability of both the intervention and the measures used.

Observations - Each group will be observed by the research team on at least one occasion. Observations will take place in the location where the group facilitator is based. The research team will meet regularly to discuss observations and these may include issues, such as internet connection, interactions between members, differences between facilitators, interventions components that appear to be translating well to the VC format and (vice-versa). This will be informed by direct observations of face-to-face groups made during Phase 1.

Evaluation point 2 – Six month follow up will involve completion of the same validated scales as at baseline and 8 weeks by those within intervention and control groups. Information on service access since previous stage of data collection will also be gathered. An optional comments box will be included for collection of qualitative data. Again, a series of semi-structured qualitative interviews with intervention group participants will also be sought (n= 5 - 8).

Waiting list control group

Participants will be informed in participant information sheets (before baseline measures are completed) that a waiting list will be in operation for this service. If participants drop out of a group within the first two weeks, a person from the waiting list control group will be selected at random to fill their place (using the same process outlined above). Persons on the waiting list control group will have been informed that they can join a face to face group at any stage. However, should those on the waiting list access AWARE NI's face-to-face group they will be removed from the study. Those on the waiting list will still have access to their own user dashboard following registration and will be kept abreast of the likely date in which their group will be starting.

Data Analysis

Descriptive statistics will be used to analyse: dropout rates (as a measure of acceptability of the intervention); to compare measures from the intervention and control group (as a measure of the potential for efficacy); number of persons who attempt to register an interest in the service (as a measure of demand for the service) and group retention (attendance during sessions). Quantitative data will also be used to inform a power calculation to determine number of participants needed for a full RCT.

Qualitative data analysis will explore: issues of acceptability (of the intervention and randomisation method); potential advantages and disadvantages of the intervention; practicalities of delivering the intervention; and around suitability of recruitment methods.

Economic Evaluation Phase

We will undertake an economic appraisal to determine the cost effectiveness of the VC intervention compared to service as usual. All resource costs used in providing the intervention will be included. Labour costs will include training of group facilitators and weekly supervision on an incremental cost basis. Capital and consumables costs will include use of premises and overheads. Out-of-pocket expenses incurred by participants and staff will also be taken into account including the opportunity costs of time spent preparing and travelling. The evaluation will produce an incremental cost-effectiveness ratio (ICER) on the basis of the primary outcome. Any uncertainty in ICER estimates will be presented in a sensitivity analysis following best practice (NICE, 2012).

PPI and user involvement

A Participatory Theme Elicitation (PTE) method will also be applied where members of an advisory panel for the study (who are not participants in the intervention or controls) will be involved in analysing qualitative data. PTE is informed by sorting procedures to structure ambiguous data (Burke et al, 2005). The main task of PTE is to identify common groupings or 'themes' present in the data as identified (in this instance) by participant researchers. PTE will involve four key steps:

1. Capacity building – short training programme delivered by core research team to build research literacy and skills of users;
2. Data selection - two members of the research team will review the qualitative transcripts and identified excerpts that could be easily understood and interpreted as standalone statements;
3. Sorting - packs containing excerpts will be printed. Sorting will then be individually performed by the participant researchers. Participants will be instructed to sort the excerpts (or quotes) into piles, based on similarity, using whatever criteria they found relevant (Rosenberg & Park Kim 2005). Additional instructions include: at least two piles and no miscellaneous pile.
4. Grouping - the grouping process will involve calculating a similarity score to identify common groups or themes.

Additional ethical considerations

As participants are defined as a vulnerable group, additional measures and safeguards will be put in place to minimize any potential harm caused by participation in this study. They are as follows;

- Measures used at baseline will include validated scales and questions previously tested on vulnerable populations. All measures will be easy for participants to read and understand and advice will be taken from a service user advisory panel formed as part the project Additional care will be taken to ensure participants understand the principles of informed consent and confidentiality (including its limits) as per good practice guidelines. The PI and main research assistant have recently undertaken Good Clinical Practice training.

- Appropriate information on the evaluation will be given to participants before they take part, allowing for informed consent. This will include a consent 'cooling off' period approximately one week before the study is due to take place.

- A designated staff member will be identified within the organisation and the researcher will not be left alone with any participants (unless they have consented to one-to-one interviews). All interviews will be conducted on AWARE NI premises or via video link.

- The PI is a qualified social worker and has received training in risk assessment as well as group-based interventions with older adults. He will be able to provide increased awareness of any individual displaying signs of distress.

- The researcher will liaise with staff to ensure that in so far as possible individuals who are not suitable are removed from the study e.g. unable to give informed consent

- No participant will be disadvantaged by taking part (or not) in the study. As such, interviews will be arranged after or before online group meetings to ensure no additional costs are incurred by participants

The researcher(s) will read and familiarize themselves with AWARE NI protocols and Several members of the research team are professionally qualified with experience in the field of mental health care. They is aware of the risks and vulnerabilities of those diagnosed with depression and will provide supervision and guidance to other members of the research team. Researchers will not be in a room alone with participants unless written consent has been provided as in the case of interviews and observations. AWARE NI staff will also be participating in observations and interviews. The CEO of AWARE NI will be informed of any interviews, focus groups or direct observations taking place with staff or service users. Proposed participants will not have been previously known by the research team.

CONSENT FORM

Title: **Development of a new online support group for adults with depression**

Name of Researcher: **Dr Paul Best**

Please initial all boxes

1. I confirm that I have read and understood the Participant Information Sheet and have had opportunity to consider the information, ask questions and have had these questions answered satisfactorily. ☐
2. I understand that my participation is completely voluntary and that I have the right to withdraw at any stage without need to give reason for doing so. ☐
3. I understand that all information and data collected by the researchers will be held securely and in confidence and give permission for the researchers to hold relevant personal data. ☐
4. I agree to the interview being audio recorded and understand that recordings will not be listened to by anyone outside of the research team. ☐
5. I agree that quotations from the interview may be used in publications and understand that any quotations used will be made anonymous. ☐
6. I consent to take part in the above study. ☐

Name of participant	Signature	Date
Name of person taking consent	Signature	Date