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We Can: a web-based skills package for carers of people with anorexia nervosa

Submission date
06/03/2017

Recruitment status
No longer recruiting

Registration date
20/03/2017

Overall study status
Completed

Last Edited
19/02/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Anorexia Nervosa (AN) is a serious eating disorder in which people keep their body weight low by dieting, vomiting, using laxatives or excessively exercising. It affects men and women of all ages, but is most common in young women. AN affects the whole body, and can lead to serious mental health issues, such as depression and problems with cognitive (thinking, learning and memory), as well as damage to major organs such as the heart and kidneys. Carers of people with anorexia nervosa play an important role in recovery, but often feel ill equipped to effectively support their loved one. Especially for carers of individuals above the age of 18 there is often little support available. This lack of knowledge and skills, potentially leads to problematic carer behaviours, such as high levels of expressed emotion or accommodation to the illness, which may worsen or maintain the illness. It also takes a toll on carers' own mental health. Therefore, there is a need for programs that support carers in their role. "We Can" is a web-based skills training programme developed for carers of people with AN that aims to target unhelpful carer behaviours and attitudes and also addresses carers' own needs. The aim of this study is to investigate how well the "We Can" programme is able to support carers of individuals with anorexia nervosa and to look at how different levels of support with the intervention may affect the results.

Who can participate?
Adult carers looking after someone aged 16 years and over who has AN.

What does the study involve?
Carers who are interested in participating in the study are asked to visit the project website. On this website, carers can access more information about the study and study team. If they are interested in taking part, carers are asked to complete a short number of questions to determine their eligibility for the project. If carers are eligible to participate and provide consent to participate, they can then create a username and password in order to start using the We Can website. Carers then have access to eight modules related to caring for a person with anorexia, released over a 12 week period. The total duration of the study is 12 months and includes a total of four online assessments. In each assessment, carers are asked to complete a range of questionnaires assessing well-being, the impact of the eating disorder, and different aspects of their role as a carer. Participants with anorexia who choose to participate are asked to complete

four online assessments which relate to well-being, eating disorder symptoms, quality of life, experience of being cared for, and the amount of support received for their eating disorder.

What are the possible benefits and risks of participating?
Anorexia impairs all aspects of the life of a person with this diagnosis, and the lives of their families. It is hoped that giving carers an intervention aimed at improving their mental health, their experience of caregiving and providing them with the skills to better care for their loved one, ultimately improves the health and well-being of both carers and individuals with AN. This may have far reaching consequences, including reduced health service costs due to the reduced need for health care for carers, as well as due to a potentially more rapid and long-lasting recovery of the individual with anorexia. Carers will be asked to complete several questionnaires on multiple occasions, as well as a web-based intervention to improve their carer skills and mental health. Carers may find it difficult or slightly distressing at times to complete the questionnaires or intervention modules, as they deal with the eating disorder of their loved one, aspects of caring, and mental health. To minimise this risk, carers can complete these questionnaires and interventions modules at their own pace. In addition, the questionnaire used in this study are very widely used and usually do not cause distress.
Individuals with anorexia in this study will be asked to complete several questionnaires on multiple occasions. Some participants may find answering these questions difficult or slightly distressing at times. To minimise this risk, participants can complete these questionnaires at their own pace and at any time. This allows them to take breaks if required and to complete these questions at a convenient time and location. In addition, the questionnaire used in this study are very widely used and usually do not cause distress.

Where is the study run from?
Maudsley Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2015 to August 2018

Who is funding the study?
European Commission (Belgium)

Who is the main contact?
Miss Lucy Spencer
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
32843

Study information

Scientific Title
We Can – a randomised controlled trial of a web-based intervention for carers of individuals with anorexia nervosa

Study objectives
The aim of this study is to investigate the effectiveness of a web-based skills package (We Can) to support carers of individuals with anorexia nervosa and to look at how different levels of support with the intervention may affect the results.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West – Greater Manchester East Research Ethics Committee, 01/02/2017, ref: 16/NU/0885

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Mental Health, Primary sub-specialty: Eating Disorders; UKCRC code/ Disease: Mental Health/ Behavioural syndromes associated with physiological disturbances and physical factors

Interventions
Carers will be allocated to one of the three intervention conditions at random, and this will be stratified by whether the person with anorexia for whom they carer is in inpatient treatment or not, and by whether the person for whom they care has agreed to provide data. Thus, there will be separate randomisation schedules for each possible combination (4) of these stratification factors. Within the randomisation schedule, carers will be randomized in a 1:1:1 ratio in the three groups (We Can-Chat, We Can-Ind and We Can-forum). Randomisation will be undertaken by an

independent biostatistician, based at the University of Muenser, using a pre¬generated list of random numbers. The researchers involved in the recruitment will be blinded to the allocation sequence.

We Can-forum: Carers will complete the We Can intervention independently and receive access to a moderated online forum, where they can communicate with other participating carers during and after the intervention (asynchronous support). The forum acts as a platform for participants to share problems, solutions and successes. Participants will be encouraged to use the forum throughout the 12-week intervention period.

We Can-Chat: In addition to the online forum carers receive access to an online chat-room, in which they can communicate with other participating carers at scheduled times. These chat session are moderated by a trained coach (synchronous support).

We Can-Ind: In addition to the online forum, carers have weekly contact with a trained coach via email to discuss any issues or for motivational support.

In all three arms, participants (i.e. carers of people with anorexia nervosa) will receive the web-based skills package (We Can), consisting of 8 modules, delivered over 12 weeks. Upon treatment completion, there is a follow up period in which participants are asked to complete assessments at 6 months post randomisation and 12 months post randomisation.

Intervention Type
Behavioural

Primary outcome(s)
Carers:
1. Depression is measured using the Patient Health Questionnaire 9 (PHQ9) at baseline, 4 weeks, 3 months (post-intervention), 6 months, and 12 months (follow-up)
2. Anxiety is measured using the Generalised Anxiety Disorder 7 (GAD7) at baseline, 4 weeks, 3 months (post-intervention), 6 months, and 12 months (follow-up)

Key secondary outcome(s)
Carers
1. Socio-demographic variables are measured using a set of questions devised by the research team at screening and baseline
2. Alcohol use is measured using the Alcohol Use Disorders Identification Test (AUDIT) at baseline, 4 weeks, 3 months (post-intervention), 6 months, and 12 months (follow-up)
3. Drug use is measured using the Drug Use Disorders Identification Test (AUDIT) at baseline, 4 weeks, 3 months (post-intervention), 6 months, and 12 months (follow-up)
4. Quality of life is measured using the Assessment of Quality of Life (AQoL)-8D, at baseline, 3 months (post-intervention), 6 months, and 12 months (follow-up)
5. Carer accommodating and enabling behaviours are measured using the Accommodation and Enabling Scale for Eating Disorders (AESED), at baseline, 3 months (post-intervention), 6 months, and 12 months (follow-up)
6. Personality is measured using the Big Five Inventory (BFI)-10, at baseline
7. Service utilization and other cost-related variables are measured using the Client Service Receipt Inventory (CSRI), at baseline, 3 months (post-intervention), 6 months, and 12 months (follow-up)
8. Resilience is measured using the Connor-Davidson Resilience Scale (CD-RISC10) at baseline, 3 months (post-intervention), 6 months, and 12 months (follow-up)

9. Treatment expectancy and rationale credibility are measured using the Credibility / Expectancy Questionnaire (CEQ), at baseline and 4 weeks
10. Caregiver Skills are measured using the Caregiver Skills (CASK) scale, at baseline, 3 months (post-intervention), 6 months, and 12 months (follow-up)
11. Impact of eating disorder symptoms is measured using the Eating Disorders Symptom Impact Scale (EDSIS), at baseline, 3 months (post-intervention), 6 months, and 12 months (follow-up)
12. Experience of caregiving is measured using the Experience of Caregiving Inventory (ECI), at baseline, 3 months (post-intervention), 6 months, and 12 months (follow-up)
13. Psychological distress is measured using the Kessler Psychological Distress Scale (K10), at screening
14. Self-esteem is measured using the Rosenberg Self-Esteem scale (RSE), at baseline and 4 weeks
15. Perceived therapeutic alliance is measured using the Working Alliance Inventory – Short Revised (WAI-SR), at 4 weeks
16. Session ratings will be measured on a 1-5 scale after the completion of each session

Individuals with Anorexia:
1. Socio-demographic variables are measured using a set of questions devised by the research team at screening and baseline
2. Alcohol use is measured using the Alcohol Use Disorders Identification Test (AUDIT) at baseline, 4 weeks, 3 months (post-intervention), 6 months, and 12 months (follow-up)
3. Quality of life is measured using the Assessment of Quality of Life (AQoL)-8D, at baseline, 3 months (post-intervention), 6 months, and 12 months (follow-up)
4. Expressed emotion is measured using the Brief Dyadic Scale of Expressed Emotion (BDSEE; Patient Version) at baseline, 4 weeks, 3 months (post-intervention), 6 months, and 12 months (follow-up)
5. Body mass index is measured at baseline, 4 weeks, 3 months (post-intervention), 6 months, and 12 months (follow-up)
6. Service utilization and other cost-related variables are measured using the Client Service Receipt Inventory (CSRI), at baseline, 3 months (post-intervention), 6 months, and 12 months (follow-up)
7. Eating disorder symptomatology is measured using the Eating Disorder Examination - Questionnaire (EDE-Q) at baseline, 3 months (post-intervention), 6 months, and 12 months (follow-up)
8. Depression is measured using the Patient Health Questionnaire 9 (PHQ9) at baseline, 4 weeks, 3 months (post-intervention), 6 months, and 12 months (follow-up)
9. Anxiety is measured using the Generalised Anxiety Disorder 7 (GAD7) at baseline, 4 weeks, 3 months (post-intervention), 6 months, and 12 months (follow-up)

Completion date
30/09/2019

Eligibility

Key inclusion criteria
Carers:
1. Aged 18 years and over
2. Caring for (providing unpaid help and support to) an adolescent (aged 16+), or adult with anorexia nervosa (including those who have been recently weight restored), as opposed to a

different eating disorder
3. Fluent in English
4. Able to access and use an internet-based intervention

Individuals with Anorexia:
1. Must be diagnosed with anorexia nervosa (including those who have been recently weight restored), as opposed to a different eating disorder
2. Must have a carer who initially agreed to participate in the study
3. Aged 16+
4. Fluent in English
5. Able to access and use the internet for the purpose of completing questionnaires

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Carers
1. Caring for a person with an eating disorder other than AN (e.g. normal weight bulimia nervosa) who has never been diagnosed with AN
2. Current eating disorder in the carer
3. Inability of the carer to read and understand English

Participants with anorexia nervosa
1. Participants who have never received a diagnosis of anorexia nervosa.
2. Currently dependent on drugs or alcohol
3. Diagnosed with a current major psychological disorder, which would interfere with the participants ability to complete the relevant questionnaires (for example, psychosis, or severe suicidal depression).
4. Under the age of 16

Date of first enrolment
01/04/2017

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Maudsley Hospital
Denmark Hill
London
United Kingdom
SE5 8AZ

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from an ICare steering board (contact email address to be confirmed at a future date).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/02/2018		Yes	No