ISRCTN14317248 https://doi.org/10.1186/ISRCTN14317248

Finding My Way UK: an investigation of the benefits of online psychological support for cancer survivors

Submission date
18/03/2021

Recruitment status
No longer recruiting

Registration date
08/04/2021

Overall study status
Completed

Last Edited
20/09/2024

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
The North West has a high rate of cancer diagnosis and deaths compared to the rest of the UK. Over one-third of cancer patients report anxiety or depression, three-quarters report psychological distress, and pilot work has confirmed high levels of psychological and supportive care needs that patients in the North West of the UK would like more support with. There is a lack of evidence about what might best reduce distress in UK cancer patients. 'Finding My Way' is a web-based programme developed in Australia. It contains six sections that help patients to better cope with the consequences of cancer treatment. In Australian research, cancer survivors who completed 'Finding My Way' reported reduced psychological distress and used fewer healthcare services. This study will test whether 'Finding My Way' is helpful to UK patients, potentially saving the NHS valuable resources.

Who can participate?
People aged 16 years and over who have received a cancer diagnosis within the last 6 months and who have received anti-cancer treatment with curative intent

What does the study involve?
Participants will be randomly allocated to one of two groups. Participants in the 'immediate access' group will receive immediate access to the Finding My Way programme, which is an online coping programme for UK-based cancer survivors. The 'waitlist control' group will immediately be provided with an information pack about other psychological services they can access. The 'waitlist control' group will then also receive access to the Finding My Way programme once they have finished all other studies activities. All participants will be sent a link to complete a series of questionnaires at the start of the study and 3 and 6 weeks after their assignment to either study group, and then again 3 months and 6 months after that. These questionnaires will ask about participants' mental health, quality of life, and health service utilisation.

What are the possible benefits and risks of participating?
Based on findings from an Australian study that tested the Australian version of Finding My Way,

the researchers have evidence to suggest that participants may experience reduced distress after completing the UK-adapted version of the Finding My Way online programme. The Australian study also found that participants who completed Finding My Way were better able to self-manage their symptoms and did not need to use as many other health care services. The risks associated with taking part in this study are low. Nevertheless, reading some material may trigger difficult thoughts and strong emotions.

Where is the study run from?
University of Chester (UK)

When is the study starting and how long is it expected to run for?
March 2020 to May 2023

Who is funding the study?
North West Cancer Research (UK)

Who is the main contact?
Prof Nick Hulbert-Williams, nick.hulbert-williams@edgehill.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Nicholas Hulbert-Williams

Contact details
Edge Hill University
St Helens Road
Ormskirk
United Kingdom
L39 4QP
+44 (0)1695 657684
nick.hulbert-williams@edgehill.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
288469

Central Portfolio Management System (CPMS)
48313

Study information

Scientific Title
Finding My Way UK: adaptation and replication testing of the benefits of online psychological support for cancer survivors

Study objectives
1. The UK-adapted Finding My Way programme reduces cancer-specific distress more than an information pack signposting local support services.
2. The UK-adapted Finding My Way programme reduces anxiety, depression and stress more than an information pack signposting local support services.
3. The UK-adapted Finding My Way programme improves quality of life more than an information pack signposting local support services.
4. The UK-adapted Finding My Way programme improves psychological adjustment to cancer more than an information pack signposting local support services.
5. The UK-adapted Finding My Way programme reduces health service utilisation more than an information pack signposting local support services.
6. Social support moderates the effect of the UK-adapted Finding My Way programme on cancer-specific distress; depression, anxiety and stress; quality of life; psychological adjustment to cancer; and health service utilisation.
7. Vulnerability to distress moderates the effect of the UK-adapted Finding My Way programme on cancer-specific distress; depression, anxiety and stress; quality of life; psychological adjustment to cancer; and health service utilisation.
8. Motivation to seek information moderates the effect of the UK-adapted Finding My Way programme on cancer-specific distress; depression, anxiety and stress; quality of life; psychological adjustment to cancer; and health service utilisation.
9. Psychological flexibility mediates the effect of the UK-adapted Finding My Way programme on cancer-specific distress.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/03/2021, Wales REC 4 (Health and Care Research Wales Support Centre, Castlebridge 4, Wales REC 4, CF11 9AB, UK; +44 (0)2920230457; Wales.REC4@wales.nhs.uk), REC ref: 21/WA/0029

Primary study design
Interventional

Study design
Randomized; Both; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Qualitative

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Online psychological support for cancer survivors

Interventions
Randomisation
Prior to the beginning of the study, the Liverpool Clinical Trials Centre will create the randomisation code for the study and set up a randomisation portal to be used by unblinded members of the research team. This system will be set up such that each participant in the study will be randomised to either the active intervention arm of the study or the waitlist control arm in a 1:1 ratio.

Intervention Arm
Participants in the intervention arm of the trial will receive immediate access to the UK-adapted Finding My Way programme. The Finding My Way programme is composed of six modules, which address the following topics:
1. Starting treatment: This module provides guidance on working with the medical team, including assertive communication and decision making.
2. Coping with physical symptoms and side effects: This module provides information about fatigue, pain, and insomnia and provides activity pacing worksheets and relaxation audio tracks.
3. Coping with emotional distress: This module covers depression, anxiety, anger and stress and includes both cognitive restructuring worksheets and mindfulness audio tracks.
4. Body image, identity, and sexuality: This module includes psychosexual worksheets and therapeutic writing activities.
5. Your family and friends: This module provides further guidance on assertive communication and needs assessment worksheets.
6. Completing treatment: This module includes self-management strategies to facilitate healthy lifestyles.

One new module is made available to participants each week, such that the Finding My Way Programme runs over a total of 6 weeks. The programme also includes one booster module summarizing key programme strategies, including sign-posting to material in the first six modules and some additional text and video content related to survivorship, which is made available to participants 1 month after the completion of the main 6-week programme.

Participants will complete a battery of questionnaires assessing their psychological functioning, quality of life and health service utilisation 3 weeks and 6 weeks after receiving access to the Finding My Way programme. The researchers will administer the same battery of questionnaires at 3-month and 6-month follow-up.

The Waitlist-Control Group
Participants in the waitlist-control group will receive an information pack signposting them to psychological support services that they can access. They will receive access to the UK-adapted Finding My Way programme after they have completed 6-month follow-up data collection.

Participants will complete a battery of questionnaires assessing their psychological functioning, quality of life and health service utilisation 3 weeks and 6 weeks after receiving their information pack. We will administer the same battery of questionnaires at 3-month and 6-month follow-up.

Intervention Type
Behavioural

Primary outcome(s)
Cancer-specific distress measured by the Post-Traumatic Stress Scale measured at baseline, mid-point assessment, post-treatment assessment, 3-month follow-up assessment, and 6-month follow-up assessment

Key secondary outcome(s)
1. Depression, anxiety, and stress measured by the Depression, Anxiety, and Stress Scales – 21 item version (DASS-21) at baseline, mid-point assessment, post-treatment assessment, 3-month follow-up assessment, and 6-month follow-up assessment
2. Quality of life measured by the European Organisation for Research and Treatment of Cancer

Core Quality of Life Questionnaire (version 3.0) (QLQ-C30) at baseline, mid-point assessment, post-treatment assessment, 3-month follow-up assessment, and 6-month follow-up assessment
3. Psychological adjustment to cancer measured by the Psychological Impact of Cancer (PIC) Scale at baseline, mid-point assessment, post-treatment assessment, 3-month follow-up assessment, and 6-month follow-up assessment
4. Health service utilisation measured by the UK Cancer Costs Questionnaire at baseline, mid-point assessment, post-treatment assessment, 3-month follow-up assessment, and 6-month follow-up assessment
5. Social support measured by the MOS Social Support Survey at baseline
6. Vulnerability to distress measured by the Difficulties in Emotion Regulation Scale at baseline
7. Motivation to seek information measured by the Miller Behavioural Style Scale at baseline
8. Psychological flexibility measured by the CompACT at baseline, mid-point assessment, post-treatment assessment, 3-month follow-up assessment, and 6-month follow-up assessment

Completion date
31/05/2023

Eligibility

Key inclusion criteria
1. Been diagnosed with cancer in the past 6 months
2. Have received anti-cancer treatment with curative intent
3. Aged 16 years or over
4. Sufficiently proficient in English to provide informed consent and use the online programme
5. Able to access the internet
6. Currently have (or willing to set up) an active email address

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 Years

Sex
All

Total final enrolment
289

Key exclusion criteria
Severe comorbidity considered by the screening nurse to interfere with the individual’s ability to complete the requirements of the study or provide informed consent (e.g., intellectual disability or neurological impairment)

Date of first enrolment
12/04/2021

Date of final enrolment
26/08/2022

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Countess of Chester Hospital NHS Foundation Trust
Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre
Betsi Cadwaladr University LHB
Executive Offices
Ysbyty Gwynedd
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
Blackpool Teaching Hospitals NHS Foundation Trust
Victoria Hospital
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital

Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
The Clatterbridge Cancer Centre NHS Foundation Trust
Clatterbridge Hospital
Clatterbridge Road
Bebington
United Kingdom
CH63 4JY

Study participating centre
East Lancashire Hospitals NHS Trust
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Bolton NHS Foundation Trust
Royal Bolton Hospital
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Stockport NHS Foundation Trust
Stepping Hill Hospital

Poplar Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre
Northern Care Alliance NHS Foundation Trust
Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
University of Chester

ROR
https://ror.org/01drpwb22

Funder(s)

Funder type
Charity

Funder Name
North West Cancer Research Fund incorporating Clatterbridge Cancer Research; Grant Codes: AR2019.08

Alternative Name(s)
North West Cancer Research Fund, NWCR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The quantitative datasets generated during and/or analysed during the current study will be stored in a publicly available repository. The researchers will share anonymised data via the Open Science Framework. These data will include the primary and secondary outcome measures, demographic and clinical data, as well as any moderating or mediating variables we ultimately include in all planned and exploratory analyses. The researchers will not include the name of participants' recruiting cancer centre in the interest of maintaining participant anonymity. Participants will explicitly consent for their anonymised data to be shared with other members of the research community.

Given the limited scope of the qualitative interview schedule, and the ethical risks involved in releasing qualitative data openly, the researchers do not currently plan to share data from this aspect of the trial. They will, however, review best practice guidelines as they change over the course of the project, and they will review this aspect of the data sharing policy at the time of project completion.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Adaptation Report and Protocol	20/09/2021	21/09/2021	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version V2	15/02/2021	08/04/2021	No	No
Protocol file	version 4	16/08/2021	08/09/2021	No	No
Protocol file	version 5	09/11/2021	28/01/2022	No	No