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A multi-site trial of specialist palliative care in cystic fibrosis

Submission date	Recruitment status	[X] Prospectively registered
15/09/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/10/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/03/2023	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

Plain English summary of protocol
Current plain English summary as of 09/03/2021:

Background and study aims
Cystic fibrosis (CF) is a genetic disease that affects more than 30,000 individuals in the United States and their families. People with CF experience multiple physical and emotional symptoms, including shortness of breath, tiredness, pain, depression, and anxiety.
Palliative care is a medical speciality of experts who work to reduce suffering and improve quality of life for people with serious illness, like CF. Although there is evidence for the benefits of palliative care in illnesses like cancer and heart disease, we do not know if it has the same benefits for people living with CF. The goal of this study is to test whether palliative care, delivered alongside usual CF care, improves outcomes for people with CF.
Aims:
1. To compare integrated palliative care to usual care for effects on patient quality of life, physical and psychological symptom burden, and advance care planning
2. To compare integrated palliative care to usual care for effects on caregiver quality of life, psychological distress and burden
3. To evaluate the mechanisms of providing integrated palliative care and barriers and facilitators to broader implementation

Who can participate?
English-speaking adults ages 18 and over who have cystic fibrosis with unmet palliative needs as indicated by: 1) one or more moderate or severe symptom, 2) reduced quality of life, and/or 3) two or more hospitalizations in the past year. Caregivers who are identified by the patient as being involved in their care also are eligible.

What does the study involve?
Participants will be assigned by chance to receive either usual CF care or usual care plus at least four visits with a palliative care nurse practitioner. The visits will address physical and emotional symptoms, participants' understanding of their condition, and goals and concerns for the future, including advance care planning.

What are the possible risks and benefits of participating?
The study includes the risk of exposure of sensitive personal information, as well as potentially uncomfortable conversations about serious illness.

Where is the study run from?
The study is led by researchers at Emory University, with additional study sites at University of North Carolina at Chapel Hill, St. Michael's Hospital (Toronto, Canada), University of California San Diego, and the University of Alabama at Birmingham. Data analysis will occur at the University of Pittsburgh.

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

Who is funding the study?
The Cystic Fibrosis Foundation

Who is the main contact?
Dr Dio Kavalieratos
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Previous plain English summary:

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3. To evaluate the mechanisms of providing integrated palliative care and barriers and facilitators to broader implementation

Who can participate?
English-speaking adults ages 18 and over who have cystic fibrosis with reduced lung function (FEV1 less than or equal to 70% of predicted), and unmet palliative needs as indicated by: 1) one or more moderate or severe symptom, 2) reduced quality of life, and/or 3) two or more hospitalizations in the past year. Caregivers who are identified by the patient as being involved in their care also are eligible.

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April 2020 to March 2024

Who is funding the study?
The Cystic Fibrosis Foundation

Who is the main contact?
Dr Dio Kavalieratos
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Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KAVALI20Q10

Study information

Scientific Title
Integrating specialist palliative care to improve care and reduce suffering: cystic fibrosis

Acronym
InSPIRe:CF

Study objectives
What is the effect of adding specialist palliative care to usual care for adults with cystic fibrosis (CF)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/09/2020, Emory University Institutional Review Board (1599 Clifton Road, Atlanta, GA 30322, USA; +1 (0)404 712 0720; irb@emory.edu) ref: STUDY00000071

Study design
Partially blinded multi-center randomized controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Cystic fibrosis in adults

Interventions
Randomization to either quarterly visits and monthly calls with a palliative care nurse practitioner embedded in the cystic fibrosis (CF) clinic, or usual CF care. The visits will address physical and emotional symptoms, participants' understanding of their condition, and goals and concerns for the future, including advance care planning.

The duration of the intervention is 9 months (quarterly visits at months 0, 3, 6, 9).

Participant randomizaton (1:1 allocation) is stratified by site with permuted blocks of varying sizes. Patient participants are randomized to control or intervention groups after providing informed consent and baseline data.

Intervention Type
Behavioural

Primary outcome measure
1. Patient quality of life, measured by FACIT-PAL at baseline and quarterly for 15 months (months 3, 6, 9, 12, 15)
2. Caregiver quality of life, measured by PROMIS Global 10 at baseline and quarterly for 15 months (months 3, 6, 9, 12, 15)

Secondary outcome measures
1. CF-specific quality of life measured by Cystic Fibrosis Questionnaire-Revised (collected monthly, primary endpoint 12 months, secondary endpoint 15 months)
2. Symptom burden measured by Memorial Symptom Assessment Scale-CF (collected monthly, primary endpoint 12 months, secondary endpoint 15 months)
3. Psychological distress measured by Hospital Anxiety and Depression Scale (HADS) (collected monthly, primary endpoint 12 months, secondary endpoint 15 months)
4. Coping measured by Brief COPE (collected monthly, primary endpoint 12 months, secondary endpoint 15 months)
5. Satisfaction with care measured by FAMCARE-16 (collected monthly, primary endpoint 12 months, secondary endpoint 15 months)
6. Healthcare utilization measured by emergency department visits, inpatient hospitalization, unplanned outpatient visits, vital status (baseline and 15 months)
7. Advance care planning measured by presence of documentation of discussion of care wishes or signed ACP documents (baseline and 15 months)

8. Caregiver burden measured by Zarit Burden Interview (collected monthly, primary endpoint 12 months, secondary endpoint 15 months)

Overall study start date
01/04/2020

Completion date
31/03/2024

Eligibility

Key inclusion criteria
1. English-speaking
2. Age ≥18 years
3. Palliative needs, as indicated by the following criteria:
3.1. ≥1 moderate or severe symptom (captured by the Integrated Palliative Outcomes Scale [IPOS]); OR
3.2. Reduced QoL (as captured by the IPOS); OR
3.3. ≥2 hospitalizations in the preceding year

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
264

Total final enrolment
264

Key exclusion criteria
1. Post lung transplant
2. Patient does not receive primary CF care from the study site or intends to transfer primary CF care elsewhere over the next year
3. Received outpatient specialty palliative care within the past 12 months
4. Lack of reliable telephone or internet access
5. Active suicidal ideation

Date of first enrolment
01/11/2020

Date of final enrolment

15/03/2023

Locations

Countries of recruitment
Canada

United States of America

Study participating centre
Emory University
1821 Clifton Road
Suite 1016
Atlanta
United States of America
30329

Study participating centre
University of Alabama at Birmingham
1713 6th Ave S
Birmingham
United States of America
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Study participating centre
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Chapel Hill
United States of America
27514

Study participating centre
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Toronto
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Study participating centre
University of California San Diego
9350 Campus Point Drive

La Jolla
United States of America
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Sponsor type
University/education

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Funder(s)

Funder type
Charity

Funder Name
Cystic Fibrosis Foundation

Alternative Name(s)
CF Foundation, CFF

Funding Body Type
Government organisation

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

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in high-impact, peer-reviewed journals of the study protocol, primary and secondary findings, fidelity plan.

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository, the Palliative Care Research Cooperative Group, palliativecareresearch.org. Deidentified data will become available within 1 year of completion of data analysis. Further details about criteria for data access will be added at a later date.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/09/2022	27/09/2022	Yes	No