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Can the outcome prioritisation tool be used to understand what is most important to patients with multiple long-term health conditions?

Submission date 10/08/2020	**Recruitment status** No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 28/04/2021	**Overall study status** Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/08/2023	**Condition category** Other	☐ Individual participant data

Plain English summary of protocol

Background and study aims
The researchers want to understand what matters most to patients aged 45 or above with multiple long-term health conditions. Other researchers have previously created a form called an outcome prioritisation tool to help patients with multiple long-term conditions to express their priorities for their healthcare. This tool has already been used in patients aged over 65, and the researchers would now like to test it in patients age 45 and above with at least two long-term health conditions. This study aims to assess how patients with multiple long-term health conditions feel how effective this form is in helping to record which aspects of their health matter the most to them in their daily lives. The researchers are also interested in understanding whether their priorities may have changed in light of the coronavirus outbreak, and understanding how they may have changed.

Who can participate?
Patients aged 45 or above and have two or more long-term conditions

What does the study involve?
Completing the questionnaire will take about 5 minutes. The questionnaire includes some questions about the participants followed by the outcome prioritisation tool, which is a short questionnaire about participants' healthcare. The researchers will not ask participants to provide any identifiable information unless they request to receive the results.

What are the possible benefits and risks of participating?
Possible benefits are that participants are helped to consider their health outcome priorities and are prompted to communicate them with their healthcare provider. There are no risks identified from participation.

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

When is the study starting and how long is it expected to run for?
August 2020 to August 2022

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
272739

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
0763, IRAS 272739

Study information

Scientific Title

Using the outcome prioritisation tool to elicit health outcome priorities of multi-morbid patients in a multi-age and multi-ethnic setting

Study objectives

This is a questionnaire study designed to test the use of the Outcome Prioritisation Tool to elicit the health outcome priorities of patients with multi-morbidity and aged 45 or above in a multi-ethnic, East Midlands setting. The researchers also aim to describe the health outcome priorities of patients by clusters of multi-morbidities and by age categories and different ethnic groups.

However, in light of the COVID-19 pandemic, the researchers have adapted their questionnaire and recruitment methods to online and remote formats, and amended the questionnaire to collect data on how the priorities of the participant group of interest may have changed in light of the COVID-19 pandemic. The researchers are currently in the process of submitting a substantial amendment for HRA approval for these changes.

That patients suffering from underlying chronic diseases are at increased risk of complications and mortality from COVID-19 infection has been well-established. The UK government has taken steps to advocate “shielding measures” for patients with significant underlying chronic health conditions that cause them to be “extremely vulnerable” from COVID-19. Proactive care and advance care planning for patients with multi-morbidity, and in particular, patients in the “extremely vulnerable” group, is now more important than ever, and incorporating the priorities of individual patients is a key part of ensuring that care is patient-centred.

The results of this study will make an important contribution towards the provision of proactive and priorities-based care for patients with multi-morbidity, including patients identified to be “extremely vulnerable” from COVID-19. The results of this study will also improve understanding of the impact of the COVID-19 pandemic on health outcome prioritisation of patients with multi-morbidity, which will facilitate clinicians and policy-makers on developing guidance and strategies of delivering of patient-centred care for patients with multi-morbidity both during the COVID-19 pandemic and in the recovery phase of the COVID-19 pandemic.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/03/2020, London - Riverside Research Ethics Committee (Level 3 Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8199; riverside.rec@hra.nhs.uk), REC ref: 20/LO/0570

Study design

Cross-sectional survey

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

GP practice

Study type(s)
Other

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
Multi-morbidity

Interventions
The responses to the outcome prioritisation tool will be described by summary statistics and reporting of the highest ranked outcomes. The responses will be separated into before the COVID-19 pandemic and the current situation, and comparisons drawn between the relative ranking of outcomes in both groups to highlight any similarities or differences to prioritisation before the COVID-19 pandemic and in the current situation.

The three responses to the Likert scale questions will also be combined and reported out of 100% as an overall mean (SD). Analyses will be carried out using the t-test to look for differences in health outcome priorities and categorical variables in the participants' demographic information (such as ethnicity). Correlations will be sought between continuous variables in participants' demographic information (such as age) and health outcome priorities.

Intervention Type
Other

Primary outcome measure
Current patient treatment priorities measured using the OPT tool at baseline

Secondary outcome measures
Pre-COVID-19 treatment priorities measured using the OPT tool at baseline

Overall study start date
03/08/2020

Completion date
06/08/2022

Eligibility

Key inclusion criteria
1. Participants who are aged 45 or above and are suffering from at least two defined, long-term physical and/or mental health conditions, with no restriction by ethnicity or gender
2. Participants who are willing to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
45 Years

Sex
Both

Target number of participants
2000

Total final enrolment
884

Key exclusion criteria
1. Participants who are aged below 45 years of age
2. Participants not suffering from at least two long-term physical and/or mental health conditions

Date of first enrolment
06/08/2020

Date of final enrolment
03/08/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hockley Farm Medical Practice
39 Hockley Farm Road
Leicester
United Kingdom
LE3 1HN

Sponsor information

Organisation
University of Leicester

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Sponsor type
University/education

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

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/03/2024

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V2.0	14/04/2020	04/05/2021	No	No
HRA research summary			26/07/2023	No	No
Basic results			29/08/2023	No	No