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TIA: a feasibility study of telemedicine in addictions

Submission date
14/11/2019

Recruitment status
No longer recruiting

Registration date
02/12/2019

Overall study status
Completed

Last Edited
07/06/2023

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Opioids are very strong painkillers that are good for acute pain and pain at the end of life but there is little evidence that they are helpful for long-term pain. Despite this, they are widely prescribed for this reason in the UK. When opioids are used for long periods of time, they cause changes in the body which mean that to stop taking them is a very unpleasant mental and physical experience – this is known as dependence.

Opioid dependence is a chronic condition with high risks. Opioid substitution treatment with methadone or buprenorphine helps to improve outcomes. Department of Health UK guidelines recommended service users prescribed opioid substitution treatment have an addictions prescriber appointment every twelve weeks. This is to help improve health, wellbeing, recovery needs and ensure medication safety.

We have found that some service users do not attend appointments. This study will see if using telemedicine for appointments helps service users attend appointments.
Telemedicine is the use of Skype video calling. Service users would see their prescriber through their healthcare workers laptop. The prescriber would be at another location. This may help reduce travel, as service users could attend an appointment near to their home

Who can participate?
Service users with opioid dependence, prescribed opioid substitution treatment, and attending an outreach clinic are eligible for the study

What does the study involve?
Service users who accept to participate in the study will be randomly assigned to either telemedicine appointments or face-to-face appointments (treatment as usual). Service users will have their next two addiction prescriber appointments as either telemedicine appointments or face-to-face appointments.

Information will be collected on attendance rates, patient satisfaction and travel distance for service users, and also from staff on their experience of Telemedicine and the trial. Information from this smaller study will be used to inform a future larger study to help develop better access to addictions treatment

What are the possible benefits and risks of participating?
Benefits to trial participants may be that this intervention helps a participant attend appointments. This would also help the knowledge base on telemedicine in addictions.
Risks: none anticipated

Where is the study run from?
East Riding Partnership - Humber NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?
September 2019 to May 2020

Who is funding the study?
1. East Riding Clinical Commissioning Group, UK
2. Academic Health Science Network, 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

259335

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
V1130619

Study information

Scientific Title
Telemedicine in Addictions Randomised Controlled Trial

Acronym
TIA

Study objectives
Telemedicine consultations may improve attendance at addiction prescriber appointments

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/08/2019, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (St Luke's Hospital, Extension Block, Little Horton Lane, Bradford, BD5 0NA, UK; +44 (0)207 104 8018; nrescommittee.yorkandhumber-bradfordleeds@nhs.net) ref: 19/YH/0237, IRAS project ID: 259335

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Opioid dependence

Interventions
Service users who accept to participate in the study will be randomly assigned to either Telemedicine appointments or face-to-face appointments (treatment as usual). Service users will have their next two addiction prescriber appointments as either Telemedicine appointments or face-to-face appointments.

Information will be collected on attendance rates, patient satisfaction and travel distance for service users, and also from staff on their experience of Telemedicine and the trial. Information from this smaller study will be used to inform a future larger study to help develop better access to addictions treatment.

The first consultation will be offered within 4 weeks of consent, the second consultation will be within 12 weeks of the first consultation, follow up interviews within 4 weeks of the second consultation. The patients will be within the study for 20 weeks.

Randomisation will be carried out after consent has been gained and the initial baseline assessment has been conducted. This will be conducted via Red Cap Cloud to randomize 60 participants into two treatment groups with 1:1 ratio, using random permuted blocks. A remote randomisation procedure will be used through Red Cap data management to generate the treatment allocation, which will be initiated by a trained researcher. It is not possible for participants and the study team to be blind to treatment allocation due to the treatment intervention.

Intervention Type
Behavioural

Primary outcome measure
Attendance at appointments measured using electronic care records

Feasibility outcomes:
1. Recruitment rate measured using a count of consent forms at follow-up (20 weeks)
2. Retention rate measured using a count of completed questionnaires at follow-up (20 weeks)
3. Acceptability of the study - views and experiences of service users and staff measured using a research interview at follow-up (20 weeks)

Secondary outcome measures
1. Patient satisfaction measured using the Patient Satisfaction Questionnaire (PSQ) and the Telemedicine Satisfaction Questionnaire (TSQ) (Telemedicine arm only) at the end of the first and second consultations
2. Travel distance measured using electronic care records
3. Addiction changes that occur during treatment measured using the Treatment Outcome Profile (TOP) and urine tests at baseline and at follow-up (20 weeks)
4. Patient and staff evaluation of the process measured using a process evaluation interview at follow-up (20 weeks)
5. Addictions prescriber satisfaction measured using a non-validated questionnaire at follow-up (20 weeks)

Overall study start date
14/12/2018

Completion date

10/06/2020

Eligibility

Key inclusion criteria
1. Diagnosis of opioid dependence
2. Prescribed opioid substitution treatment (OST) e.g. methadone or buprenorphine
3. Aged 18 years to 65 years
4. Willing and able to provide informed consent
5. Attending an outreach (spoke) clinic for keyworker appointments

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Service users who cannot read English AND would require the service of an interpreter to understand a brief oral description of the study
2. Service users who have already entered the trial

Date of first enrolment
24/09/2019

Date of final enrolment
28/02/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

East Riding Partnership - Humber Teaching NHS Foundation Trust
7 Baker Street
Hull
United Kingdom
HU2 8HP

Sponsor information

Organisation
Humber Teaching NHS Foundation Trust

Sponsor details
Trust HQ
Willerby Hill
Beverley Road
Willerby
England
United Kingdom
HU10 6ED
+44 (0)1482 301723
hnf-tr.ResearchTeam@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.humber.nhs.uk/

ROR
https://ror.org/016bnqk64

Funder(s)

Funder type
Government

Funder Name
East Riding Clinical Commissioning Group

Funder Name
Academic Health Science Network

Results and Publications

Publication and dissemination plan
Results will be published in scientific papers and made available to participants (through a poster with summary results put up in participating site waiting areas).
A summary of the results will be presented at the Humber Teaching NHS FT clinical network and Research and Development annual Conference.
The protocol and findings will be published in an academic journal.

Intention to publish date
01/05/2022

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. Hull Health Trials Unit, University of Hull, using two cloud based systems – REDCap Cloud and Box.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		13/06/2019	05/12/2019	No	No
Abstract results	Participant and staff satisfaction results presented at the Royal College of Psychiatrists Virtual International Congress	18/06/2021	06/09/2021	No	No
Abstract results	Participant experience data presented at the Royal College of Psychiatrists Virtual International Congress	18/06/2021	06/09/2021	No	No
Other publications	Title: Patient Satisfaction with Telemedicine in Addictions	01/08/2021	06/12/2021	Yes	No
HRA research summary			28/06/2023	No	No