







TIA: a feasibility study of telemedicine in addictions

Submission date 14/11/2019	Recruitment status No longer recruiting	 Retrospectively registered
Registration date 02/12/2019	Overall study status Completed	 Protocol added
Last Edited 07/06/2023	Condition category Mental and Behavioural Disorders	 SAP not yet added
		 Results added
		 Raw data not yet added
		 Study completed

Plain English Summary

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

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

259335

ClinicalTrials.gov number

Nil known

Protocol/serial number

V1130619

Study information

Scientific Title

Telemedicine in Addictions Randomised Controlled Trial

Acronym

TIA

Study hypothesis

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

Condition

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

Overall study end date

10/06/2020

Eligibility

Participant 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

Participant 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

Recruitment start date

24/09/2019

Recruitment end date

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-publicly 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