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My Health Tags - To improve taking tablets for he

Submission date	Recruitment status	[ ] Prospectively registered
12/07/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/07/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/05/2021	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
People with long term health problems such as heart failure sometimes don't take all their suggested medications (poor compliance). One reason is that people forget to take their medicine at the prescribed time. This can result in worsening health, more hospital admissions and a reduced quality of life for the person, as well as higher health service costs. By helping patients to take their heart failure medicines regularly every day, patients are more likely to keep well and free of heart failure symptoms. In turn this can help prevent admission to hospital and improve quality of life. One study has shown that if medicine taking is better, there is an improvement in life expectancy. This small study aims to find out how well an electronic reminder system (My Health Tag) is, to help improve compliance in patients with heart failure. My Health Tag is a small electronic device that will remind patients when to take their heart failure tablets. There are two parts to the device. One is attached to the tablet packet and will alert the participant about which tablet is due to be taken. The other part is a reminder display which can be placed in the home separately from the tablets and will remind them that they are due to take some tablets.

Who can participate?
Adult with heart failure who live in the Bristol area who are currently taking medication for heart failure.

What does the study involve?
Participants are randomly allocated to one of two groups. Both groups receive the My Health Tag device and standard care in a random order. At the start of the study, participants have their medical and medication history take, as well as having their current levels of breathlessness and heart health measured. Participants who have been allocated to receive the device for the first four weeks (group AB) are shown how to use the device, which is programmed by the study team to remind them when to take their heart failure tablets. Participants assigned to standard care for the first four weeks (Group BA) are shown how the device works but it is not installed at this point. After four weeks, the two groups switch treatments so the group with the device receives standard care and the standard care group receives the device. At the end of each four week period, both groups have their heart failure tablets counted, are asked about any new health problems and have their breathlessness levels assessed. A blood and urine sample is also collected from the participant and they are asked to post another urine sample to the research team two weeks later.

What are the possible benefits and risks of participating?
There are no direct benefits to participants other than the knowledge that they may be helping to improve care for all future patients. Participants may appreciate the additional contact from the research team. It is possible that the reminder system will help participants to get into good habits of remembering to take their medication on time. There is a small risk of bruising or pain when the blood samples are taken and it is possible the technology may fail or the participant becomes completely reliant on the device to remind them to take their tablets.

Where is the study run from?
Bristol Heart Institute (UK)

When is the study starting and how long is it expected to run for?
March 2015 to December 2016

Who is funding the study?
Small Business Research Initiative Healthcare (UK)

Who is the main contact?
Ms Ruth Bowles
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Contact information

Type(s)
Public

Contact name
Ms Ruth Bowles

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20872

Study information

Scientific Title
A single centre, randomized, crossover early stage clinical study to evaluate the effects of my health tag on improving medicines adherence in patients with heart failure

Study objectives
The aim of this feasibility study is to evaluate the usefulness of an electronic reminder system (My Health Tag) in improving medication compliance in patients with chronic heart failure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Exeter Research Ethics Committee, 06/04/2016, ref: 16/SW/0032

Study design
Single-centre randomised crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home

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
Specialty: Cardiovascular disease, Primary sub-specialty: Heart failure; UKCRC code/ Disease: Cardiovascular/ Hypertensive diseases

Interventions
Following informed consent all participants will have a medical and medication history taken. They will undergo ECG, blood pressure, breathlessness and heart rate measurements.

All patients will participate in both arms of the study. The order will be determined using a random number table, generated independently by the study statistician. The assignment will be provided via sealed envelopes that are sequentially numbered and opened in number order.

Study arm AB (receive My Health Tag for first 4 weeks, followed by standard care for 4 weeks): Participants assigned to receive the device for the first 4 weeks will be shown how to use the device and the device will be programmed to remind them when to take their heart failure

medications. Their heart failure medications will be counted and they will complete a quality of life and a medication adherence questionnaire, they will also be asked if any new health problems have occurred. A blood and urine sample will be collected from the participant and they will be asked to post another urine sample to the research team 2 weeks later. At the end of the 4 weeks the My Health Tag device will be removed. Participants will be reminded to take their medications as per standard care. Their heart failure medications will be counted and they will complete a quality of life and a medication adherence questionnaire, they will also be asked if any new health problems have occurred and their level of breathlessness will be assessed. A blood and urine sample will be collected from the participant and they will be asked to post another urine sample to the research team 2 weeks later. At the end of the second 4 weeks (week 8) their heart failure medications will be counted and they will complete a quality of life and a medication adherence questionnaire, they will also be asked if any new health problems have occurred and their level of breathlessness will be assessed. A blood and urine sample will be collected from the participant. This will be the end of all study participation for the participant.

Study arm BA (receive standard care for first 4 weeks, followed by My Health Tag device for 4 weeks):
Participants assigned to standard care for the first 4 weeks will be shown how the device works but it will not be installed at this point.
Their heart failure medications will be counted and they will complete a quality of life and a medication adherence questionnaire, they will also be asked if any new health problems have occurred. A blood and urine sample will be collected from the participant and they will be asked to post another urine sample to the research team 2 weeks later. At the end of the 4 weeks participants will be shown how to use the My Health Tag device and the device will be programmed to remind them when to take their heart failure medications. Their heart failure medications will be counted and they will complete a quality of life and a medication adherence questionnaire, they will also be asked if any new health problems have occurred and their level of breathlessness will be assessed. A blood and urine sample will be collected from the participant and they will be asked to post another urine sample to the research team 2 weeks later. At the end of the second 4 weeks (week 8) the My Health Tag device will be removed. Their heart failure medications will be counted and they will complete a quality of life and a medication adherence questionnaire, they will also be asked if any new health problems have occurred and their level of breathlessness will be assessed. A blood and urine sample will be collected from the participant. This will be the end of all study participation for the participant.

Intervention Type
Other

Primary outcome measure
Percentage of ACE/ARB and Beta Blocker heart failure tablets taken during the study period, calculated from the pill count taken by the research nurse at baseline, 4, and 8 weeks

Secondary outcome measures
1. Mean difference between groups, in the proportion of patients with chronic heart failure taking >80% of prescribed pills (ACEi/ARB and BB) over a four-week period
2. Mean difference between groups in change in MMAS-8 scores measured at baseline, 4, and 8 weeks between baseline and the end of the treatment block
3. Mean difference between groups in change in urine metabolite numbers, measured at baseline, 2, 4, 6 and 8 weeks between baseline and the end of the treatment block

Overall study start date
17/03/2015

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Age over 18 years
2. Able to provide informed consent
3. Diagnosis of heart failure made more than one month prior to enrollment
4. On medication for heart failure including ACEi/ARB and B-blocker
5. Has 4 week supply of ACE/ARB and B blocker
6. Live in postcode areas BS1 – BS16
7. Able to read and understand instructions in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria
1. Medication given by partner or other care-provider
2. Use of dosette box
3. History of advanced dementia
4. Planned travel away for home for more than 7 consecutive days during the study period
5. 3G and WiFi signal absent or very poor in patient's home
6. Expected to change dose of ACEi/ARB or BB during the study period

Date of first enrolment
15/04/2016

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Heart Institute
Upper Maudlin Street
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
Small Business Research Initiative Healthcare

Results and Publications

Publication and dissemination plan
Publication and dissemination of study results is planned. Local publication on Trust website, journals, and conferences. A summary of the study will be made available to the participants and other interested parties.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No