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Supporting better medication adherence in the community for people with dementia using Biodose Connect® and appropriate education

Submission date
25/02/2016

Recruitment status
No longer recruiting

Registration date
02/03/2016

Overall study status
Completed

Last Edited
02/03/2016

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Alzheimer's disease (AD) is the most common cause of dementia, creating problems with memory, thinking and behaviour (cognitive function). People with AD often take more than one medication and managing this can be especially difficult for both the patient and their carer. The majority of people with dementia live in their own homes and wish to stay there as long as possible however when important medications are missed or taken incorrectly then the risk of symptoms worsening and of being admitted to a care home or hospital increases. This study offers patients and the carers the chance to try a new monitored dosage system called Biodose Connect. It consists of a tray containing small individual pods containing the patient's medications. When each dose is due the pod lights up, and if the medicine is not taken then it can play a recorded voice reminder message. Information about when a patient takes their medication is automatically transmitted and stored on a computer and their carer or healthcare professional can be alerted if key doses are missed to help support the patient. The aim of this study is to test the find out if the Biodose Connect device together with a tailored support programme providing information about the importance of taking medications correctly is able to improve medication adherence in people suffering from AD.

Who can participate?
Adults with AD who live at home and are taking more than one oral (by mouth) medication.

What does the study involve?
All participants are given the Biodose Connect system to use for three months. Patients and their carers are also given an opportunity to take an educational programme designed to support the will and intent to take their mediation properly and provide a better understanding of the particular reasons why this is important. The Biodose Connect system is dispensed from a Rowlands pharmacy in the community and delivered directly to the patient's home on a weekly basis for a total of 12 weeks. At the start of the study and after 12 weeks, particpants and their carers complete questionnaires in order to find out how well they feel the Biodose Connect

system has worked for them with regards to patients taking their medications properly. The clinical team also review how well the patients are taking the medications using information that is automatically transmitted from the Biodose Connect system.

What are the possible benefits and risks of participating?
Participants could benefit from being able to better manage the medication that the patients need to take, which could make their treatment more effective (as they are taking it properly). Risks of taking part are very small, however there is a risk of confusion in some patients arising from the change to how they take their medication.

Where is the study run from?
Pinderfields Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2014 to March 2015

Who is funding the study?
Quantum Pharmaceutical (UK)

Who is the main contact?
Mr Mark Dodd
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

BCDem001

Study information

Scientific Title
Biodose Connect® combined with Psycho-education: A novel intervention enhancing medication adherence and assessment of associated outcomes in people with dementia in the community setting

Acronym
BioCPED

Study objectives
Within a community population of Alzheimer's Dementia patients where poor medication adherence has both clinical and resource implications, to demonstrate the value of the Biodose Connect device coupled with a tailored psycho-education adherence support programme through satisfaction and clinical utility scores from the patients and associated healthcare professionals. To evaluate the adherence support programme by showing an improved adherence score from study baseline to endpoint.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Other

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
Early Alzheimer’s Dementia

Interventions

People with early Alzheimer's dementia known to the clinical team will be stratified and selected according to the selection criteria and inclusion and exclusion criteria. They will be offered the choice to enter the evaluation programme being provided with the combination of the novel new Biodose Connect® device together with psycho-educational support on their medication optimisation provided by nominated healthcare professional and offered to both patient and their carer. The Biodose Connect® intervention will consist of a permanent solid device into which the patient's Biodose medication tray is placed and turned on. This will be delivered to the patient's home by the community pharmacist team (Rowlands Pharmacy supporting this evaluation) and set up in the patient's home. The patient's individual medication requirements, windows of time which configure the dashboard and specific consented contacts are entered into the software programme for the patient at the start by the community pharmacist. This dictates the timings, content and to whom the reminders for missed medications are directed. It also provides details of when and to whom medication critical alerts should be sent via SMS messages or email. The real time secure dashboard for all patients patterns of medication adherence can be accessed by a secure password protected log in with nominated health care professional or carer only having access to this adherence data for review, actions and management follow up evaluation.

Each patient who consents to receive their medications in this device will be on the service for 12 weeks from baseline. At baseline the patient will be assessed using the 8-item Morisky Medication Adherence Scale (MMAS8) to establish the level of medication adherence. At the end the 12 week period the same assessment tool information will be gathered. Additionally the clinical team at the Trust will provide qualitative information on the historic pattern of adherence for each patient and resource implications related to any non-adherence e.g. re-admissions to care homes or nursing homes. The clinical team will review the patient during the 12 weeks on service with regards to enhanced patterns of adherence utilising the data from the patient's Biodose Connect® dashboard showing the pattern of adherence, doses missed, late doses and time each dose of medication was accessed.

Once the 12 weeks on service are completed, if there is clinical support, patient preference and judgment of benefit, then there will be a request to primary care commissioners to support continuation on a value based assessment on Biodose Connect®. All patients will be able to continue on the same Biodose tray (un-connected) if they wish after the review is completed.

Intervention Type
Device

Primary outcome measure
Satisfaction and clinical utility of the adherence support programme is measured using patient note review and patient and carer interviews at baseline and after 12 weeks on service.

Secondary outcome measures
Medication adherence is measured at baseline and study end point using an adherence assessment tool (MMAS-8) to establish the level of medication adherence. In addition, data on medication adherence will be collected from the Biodose dashboard between baseline and three months.

Overall study start date
01/04/2016

Completion date

30/09/2016

Eligibility

Key inclusion criteria
1. Male or female
2. Diagnosis of Alzheimer’s disease
3. Managed in community setting
4. On more than one oral medication
5. Willing and able to provide informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
12

Key exclusion criteria
1. Unable to provide fully informed consent
2. Admitted to hospital or care home/nursing home
3. Non-Alzheimer's dementia

Date of first enrolment
11/04/2016

Date of final enrolment
01/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Pinderfields Hospital
Mid Yorkshire Hospitals NHS Trust
Aberford Road
Wakefield
United Kingdom
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Sponsor information

Organisation
Quantum Pharmaceutical

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Sponsor type
Industry

Website
http://www.biodose.co.uk/index.php

ROR
https://ror.org/00yerav41

Funder(s)

Funder type
Industry

Funder Name
Quantum Pharmaceutical

Results and Publications

Publication and dissemination plan
Once completed and evaluated the intention is to utilise the outcomes for publication in a journal related to the management of Alzheimer’s dementia or care of the elderly and to use the outcomes to support a value proposition supporting such interventions in such cohorts of patients in the community setting enhancing patient benefits and reducing the burden and consequences of poor medication adherence.

Intention to publish date
01/11/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request