HEalth CHecks for adults with learning Disabilities (HECHID)

Submission date 11/11/2012	Recruitment status No longer recruiting	Prospectively registered	
		[] Protocol	
Registration date 20/11/2012	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited 29/09/2015	Condition category Mental and Behavioural Disorders	Individual participant data	

Plain English summary of protocol

Background and study aims

People with intellectual disabilities experience considerable health inequalities compared with the general population. They also have a different pattern of health needs, and their health needs are often not well met. To try to address this, the general practitioner contract in England and Wales has introduced payment to GPs if they conduct an annual health check with the adults with intellectual disabilities who are registered at their practice. Scotland did not introduce this, in view of the limited evidence on whether health checks are effective with this population. The aim of this study is to evaluate the effectiveness and cost-effectiveness of a practice nurse led health check for adults with intellectual disabilities, compared with usual treatment only.

Who can participate?

Adults with intellectual disabilities aged 18 years and over, registered at the participating general practices.

What does the study involve?

All participants are interviewed and have their GP records inspected at the start of the study. They are then randomly allocated to either the health check group or the usual treatment group. Participants in the health check group are offered a health check with their practice nurse. This involves filling in a health questionnaire before the appointment, then discussing this with the nurse at the appointment, and answering some more health questions, having a selected physical examination and urine test. The usual treatment group do not have a health check, they just have their usual treatment. Three, six, and nine months after group allocation, participants have another interview, and at nine months, their GP records are inspected again.

What are the possible benefits and risks of participating?

If the health check is effective, then participants in that group will benefit from it. If it is effective, then at the end of the study, the participants in the usual treatment group will also be offered a health check with their practice nurse. If the health check is not effective, then there will be no personal benefit from taking part in the study, other than informing the evidence base for health care of others in the future.

We do not anticipate any side effects to the health checks, but participants and their carers will have to give up some time to have the health check, and also to talk to the researchers.

Where is the study run from? 60 general practices in the NHS Greater Glasgow and Clyde area will take part. The research team are based at the Institute of Health and Wellbeing at the University of Glasgow.

When is the study starting and how long is it expected to run for? December 2010 to February 2013.

Who is funding the study? The Scottish Government (UK).

Who is the main contact? Professor Sally-Ann Cooper Sally-Ann.Cooper@Glasgow.ac.uk

Contact information

Type(s) Scientific

Contact name Prof Sally-Ann Cooper

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers Version 3

Study information

Scientific Title Practice nurse health checks for adults with intellectual disabilities: a randomised controlled trial

Acronym HECHID

Study objectives

Health checks with practice nurses improve the detection and management of health needs, health monitoring needs, and health promotion needs of adults with intellectual disabilities.

Ethics approval required Old ethics approval format

Ethics approval(s) Research Ethics Committee - Scotland A, 25/11/2010, ref: 10/MRE00/79

Study design

Matched-pair cluster randomised controlled trial plus a cost-effectiveness study and a qualitative sub-study

Primary study design Interventional

Secondary study design Cluster randomised trial

Study setting(s) GP practice

Study type(s) Quality of life

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

Intellectual disabilities

Interventions

Participants randomised to the intervention arm receive a health check with their practice nurse. The health check is a one-off procedure. It involves first the participant and their carer completing a health questionnaire, which they take with them to the appointment with the practice nurse. At the appointment with the nurse, the questionnaire is reviewed, and the nurse asks further health questions using the health check tool, completes a selected physical examination, and tests the participants urine. She then uses her clinical judgement and experience to follow through with any further appointments, investigations, or treatments that are clinically indicated, and can call upon the learning disabilities service if required.

Participants randomised to the treatment as usual group do not receive a health check or any intervention above their usual treatment.

Both study arms are followed up at 3, 6, and 9 months post randomisation.

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

Between group difference in the incidence of new health needs detected and new health needs being met during the 9 month period following randomisation (data from primary health care records interpreted at the blinded consensus meetings)

Secondary outcome measures

1. Between group difference in the extent of health monitoring needs being met (quality and outcome framework data from primary health care records)

 2. Between group difference in the extent of health promotion needs being met (data from interview and primary health care records interpreted at the blinded consensus meetings)
3. Between group difference in the change in participant/carer rated general health (scores on SF-36 and EO-5D)

4. Between group difference in costs (data from the client service receipt inventory)

5. Cost-effectiveness of the intervention compared with treatment-as-usual, in terms of cost per quality adjusted life year

Overall study start date

02/12/2010

Completion date 28/02/2013

Eligibility

Key inclusion criteria

1. Adults with intellectual disabilities aged 18 years and over

2. Registered at one of the 60 participating practices

Participant type(s) Patient

Age group Adult

Lower age limit 18 Years

Sex Both

Target number of participants 150

Key exclusion criteria

1. Unable to obtain consent in keeping with the Adults with Incapacity (Scotland) Act (e.g. person delines, their relative declines, they do not have a relative or welfare guardian/attorney) 2. Terminal illness

3. The person's GP considers it inappropriate to invite the adult (e.g. due to family circumstances such as a recent death of a parent)

Date of first enrolment 02/12/2010

Date of final enrolment 01/12/2011

Locations

Countries of recruitment Scotland

United Kingdom

Study participating centre University of Glasgow Glasgow United Kingdom G12 0XH

Sponsor information

Organisation NHS Greater Glasgow and Clyde (UK)

Sponsor details c/o Dr Erica Packard Research and Development Central Office The Tennent Institute Western Infirmary 38 Church Street Glasgow Scotland United Kingdom G11 6NT +44 (0)141 2116208 Erica.Packard@ggc.scot.nhs.uk

Sponsor type Hospital/treatment centre Website http://www.nhsggc.org.uk/

ROR https://ror.org/05kdz4d87

Funder(s)

Funder type Government

Funder Name Scottish Government - Change Programme (UK)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2014		Yes	No