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A novel approach to GP-patient interactions to improve outcomes in older people with high blood pressure

Submission date
06/10/2022

Recruitment status
No longer recruiting

Registration date
17/01/2023

Overall study status
Completed

Last Edited
12/11/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
High blood pressure (hypertension) is a preventable cause of heart disease and death. Medications can help to control blood pressure, but studies show that up to half of people do not take their blood pressure medication as directed. Despite this, discussions around challenges to taking medications and solutions to support medication taking are not a routine part of GP-patient consultations. GPs may prescribe medication and assume that the patient is taking it in the correct way. However, the patient may find it difficult to take their medication for a variety of reasons. Often during GP-patient consultations there is no space made for dialogue and decision-making to address challenges to taking blood pressure medication. Researchers have developed a tool, the MIAMI intervention, to help GPs and patients to talk about taking blood pressure medication. The aim of this study is to find out if this tool is acceptable to patients and GPs.

Who can participate?
Patients with a confirmed diagnosis of hypertension on two or more anti-hypertensive medications

What does the study involve?
Participating GP practices are randomly allocated to the MIAMI intervention or to continue with usual care. In the practices that use the MIAMI intervention the GPs will watch some training videos on challenges to medication taking and learn about some solutions. The patients will use an ambulatory blood pressure monitor to get an accurate reading of their blood pressure and do a urine test to see if they are taking their blood pressure medication. Then they will meet their GP to discuss the results and their GP will provide some solutions if needed (e.g. asking the pharmacy for a blister pack, or directing the patient to the Croí website to learn more about blood pressure). In the three other practices, everything will continue as usual. All patients will provide some data at the beginning and the end of the study (e.g. blood pressure readings, a questionnaire about health and wellbeing). All GPs will also provide some data (e.g. length of time practicing as a GP, practice size). Some patients and GPs will be asked to take part in a short interview about their experience in the study but this will be optional. This will give important

information about the acceptability of the MIAMI intervention. The researchers will also keep a track of data such as how long it took to recruit GP practices and patients, whether any GPs or patients left the study and how long it takes GPs and patients to fill in the questionnaire. This will provide more important information about how acceptable this study is.

What are the possible benefits and risks of participating?
Participants will be provided with an ambulatory blood pressure monitor twice during this study which will give an accurate reading of their blood pressure. The researchers will also provide participants with a €20 One4All voucher at the beginning and at the end of the study as an acknowledgement of their contribution to the study. If the GP practice is in the intervention arm of the study, participants will have an opportunity to discuss their current medication with their GP and be provided with support to help them take their medication as required
Participants will be required to make several visits to their GP practice, which may be a demand on their time. A data breach is always a risk, but there are measures in place to ensure that the risk is very minimal. Participants' GPs will have the results of their urine test, which will show if their blood pressure medication is present or absent. This will be an opportunity to discuss their medication taking habits. Some patients may find this uncomfortable but previous studies have shown that most patients do not have any difficulties with this.

Where is the study run from?
University of Galway (Ireland)

When is the study starting and how long is it expected to run for?
August 2021 to October 2023

Who is funding the study?
Health Research Board (Ireland)

Who is the main contact?
Dr Eimear Morrissey, eimear.morrissey@universityofgalway.ie

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HRB DIFA 2020-012

Study information

Scientific Title
Supporting GPs and people with hypertension to maximise medication use to control blood pressure: the MIAMI cluster pilot randomized controlled trial

Acronym
MIAMI

Study objectives
The aim of the MIAMI cluster pilot randomized controlled trial (RCT) is to gather and analyse acceptability and feasibility data to (1) refine the MIAMI intervention, and (2) determine the feasibility of a definitive RCT. Specifically, the MIAMI pilot cluster RCT has the following objectives:
1. To investigate if the MIAMI intervention is feasible and acceptable to GPs and people with hypertension
2. To collect pilot qualitative and quantitative data to assess the feasibility of recruitment, retention and outcomes used
3. To conduct a pilot health economic assessment of the MIAMI intervention
4. To inform the sample size calculation, including the optimal number of GP practices (clusters) and people with hypertension (participants), for a definitive cluster RCT

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/08/2022, Research Ethics Committee of the Irish College of General Practitioners (Irish College of General Practitioners, 4-5 Lincoln Place, Dublin 2, D02 XR68, Ireland; +353 (0)1 6763705; research@icgp.ie), ref: ICGP_REC_22_014

Study design
Pilot cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Hypertension

Interventions
The MIAMI intervention is a structured set of supports for GPs and patients with hypertension to facilitate adequate information exchange about long-term antihypertensive medication use and adherence skill development.

Patient intervention:
1. Blood pressure measurement using an ambulatory blood pressure monitor
2. Providing a urine sample for a chemical urine test of adherence
3. A brief 'pre-consultation plan' to be filled in before a GP consultation. This asks the patient 'Is there anything you want to discuss with your GP in relation to your blood pressure?' and prompts the patient and GP to write down an 'agreed plan'.
4. Blood pressure education through written and video material

GP intervention components:
1. Training in how to structure a consultation around adherence issues. This will be provided through educational videos, using a mixture of information and case studies
2. Booklet containing up-to-date prescribing guidelines
3. A drop-down menu on GP software which will provide a reminder of the 'pre-consultation plan' and a list of resources that can be recommended to the patient (e.g. medication reminders - dontforget.ie and blood pressure education materials

As this is a pilot study, the researchers will be open to further refinement of intervention throughout the study.

Randomization: Three GP practices will be randomized to the MIAMI intervention arm and three will be randomized to the usual care control arm. The code to generate the randomization plan will be written in R (using a reproducible random generation seed) and implemented by an independent statistician.

Intervention arm: Participants in the intervention arm will receive the MIAMI intervention at a minimum of one clinic appointment during a 3-6 month period.
Control arm: Participants in the control group will receive usual care.

Data collection will occur at two timepoints - baseline and follow-up (3-6 months later).

Intervention Type
Behavioural

Primary outcome(s)
Acceptability and feasibility of the intervention and a future definitive RCT. This will be measured through:
1. Recruitment of GP practices will be assessed by documenting the number of invitations sent, the number of refusals and the number of acceptances throughout the study
2. Recruitment of patients will be assessed by documenting the number of invitations sent, the number of initial responses, the number of follow-up phone calls required, the number of refusals and the number of acceptances throughout the study
3. Attrition of participants will be documented at every timepoint throughout the study
4. Levels of missing data in returned questionnaires will be reported at baseline and follow up

5. The comprehensibility and acceptability of all questionnaires will be measured by asking participants how the questionnaires might be improved and how long they took to complete at baseline and follow up

6, The perceptions and experiences of people with hypertension and GPs of participating in the MIAMI intervention and their views as to the feasibility and acceptability of the intervention, explored using qualitative interviews at the mid-point of the intervention

Key secondary outcome(s))
1. Systolic blood pressure (ambulatory blood pressure monitoring [ABPM], average reading) measured at baseline and follow up
2. Diastolic blood pressure (ABPM, average reading) measured at baseline and follow up
3. Blood pressure control (ABPM, reading above or below 140/90mmHg) measured at baseline and follow up
4. Medication adherence (urine screen, prescription refill records, Medication Adherence Report Scale (MARS) measured at baseline and follow up
5. Beliefs about medication (Beliefs about Medication Questionnaire (BMQ), Illness Perceptions Questionnaire - Revised (IPQ-R) 'treatment control' and 'consequences' items) measured at baseline and follow up
6. Habit strength measured using the Self-Report Behavioural Automaticity Index (SRBAI) at baseline and follow up
7. Pill burden (type and dosage) measured at baseline and follow-up
8. Health related quality of life measured using EuroQol-5D-5L at baseline and follow-up
9. Wellbeing measured using ICEpop CAPability measure for Older people (ICECAP-O) at baseline and follow up

Completion date
30/10/2023

Eligibility

Key inclusion criteria
Inclusion criteria for patient participants:
1. Have a confirmed diagnosis of hypertension
2. Participants must be on two or more anti-hypertensive medications
3. Participants must not be achieving recommended blood pressure levels i.e. clinic readings are higher than 140/90 mmHg or day ABPM 135/85 mmHg
4. In the judgement of the GP regarding a change in medication, the balance of risk/benefit lies in favour of benefit

Inclusion criteria for GP practices:
1. Within the catchment area of the biochemistry lab at University Hospital Galway
2. Using Socrates software system

Inclusion criteria for GP participants:
Doctors who are providing patient care in the practice

Healthy volunteers allowed
No

Age group

Mixed

Sex
All

Key exclusion criteria
Patient participants:
1. Unable to give informed consent
2. Resident in a nursing home

Date of first enrolment
01/11/2022

Date of final enrolment
01/04/2023

Locations

Countries of recruitment
Ireland

Study participating centre
Turloughmore Medical Centre
Athenry,
Co. Galway
Ireland
H65 H599

Study participating centre
Ballyvaughan Primary Care Medical Centre
Ballyvaughan
Lisdoonvarna Road
Co. Clare
Ireland
H91 W8WH

Study participating centre
Claddagh Medical Centre
The Crescent
Galway
Ireland
H91 EA37

Study participating centre
Main Street Clinic Loughrea
Main Street
Loughrea
Ireland
H62 X252

Study participating centre
Burren Medical Centre
Market Street
Laghtagoona
Corofin
Ireland
V95 FAW9

Sponsor information

Organisation
University of Galway

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. The anonymised quantitative data will be uploaded to osf.io under a CC0 licence as recommended by HRB Open and will be openly accessible. There will not be any restrictions on the re-use of the data. This will happen in 2023, once the pilot trial is complete. The data will be stored and accessible on this platform indefinitely. The qualitative data will not be shared due to privacy concerns.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/11/2024	12/11/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes