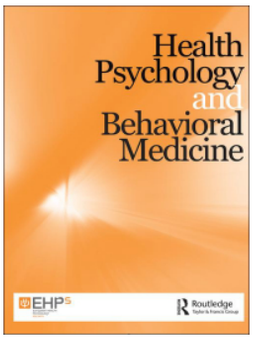

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Supporting General Practitioners and people with hypertension to maximise medication use to control blood pressure: the contribution of Collective Intelligence to the development of the 'Maximising Adherence, Minimising Inertia' (MIAMI) intervention

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ABSTRACT

Background: Hypertension remains one of the most important modifiable risk factors for stroke and heart disease. Anti-hypertensive medications are effective, but are often not used to maximum benefit. Sub-optimal dosing by prescribers and challenges with medication-taking for patients remain barriers to effective blood pressure control.

Objectives: We aimed to systematically develop a theory-based complex intervention to support General Practitioners (GPs) and people with hypertension to maximise medication use to control blood pressure.

Methods: We used the three-phase Behaviour Change Wheel (BCW) as the overarching intervention development framework. Collective Intelligence methodology was used to operationalise the stakeholder input to Phases 2 and 3 of the BCW. This took the form of a Collective Intelligence workshop with 19 stakeholders from diverse backgrounds including lived experience, general practice, nursing, pharmacy and health psychology. Techniques such as barrier identification, idea-writing and scenario-based design were used to generate possible intervention options. Intervention options were then selected and refined using the Acceptability, Practicability, Effectiveness, Affordability, Side-effects and Equity (APEASE) criteria and guidance from the MIAMI Public and Patient Involvement Panel.

Results: The finalised MIAMI intervention consists of both GP and patient supports. GP supports include a 30-minute online training,

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Hypertension; intervention development; behaviour change wheel; collective intelligence; complex intervention

SUSTAINABLE DEVELOPEMENT GOALS

SDG 3: Good health and well-being

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information booklet and consultation guide (drop-down menu) embedded within the patient electronic health system. Patient supports include a pre-consultation plan, website, and a structured GP consultation with results from an Ambulatory Blood Pressure Monitor and urine chemical adherence test. The intervention components have been mapped to the intervention functions of the BCW and Behaviour Change Technique Ontology.
Conclusion: Collective Intelligence offered a novel method to operationalise stakeholder input to Phases 2 and 3 of the BCW. The MIAMI intervention is now at pilot evaluation stage.

Introduction

Hypertension is one of the most important risk factors for stroke and heart disease. International comparisons have shown that Ireland has relatively high levels of inadequately managed blood pressure (BP) (Zhou et al., 2019). Recent international guidelines have stated that 'poor adherence to treatment – in addition to physician inertia – is the most important cause of poor BP control' (McEvoy et al., 2024). Problems with medication taking, or 'poor adherence' are very common in hypertension, with rates between 30%–50% (Hameed & Dasgupta, 2019; Lawson et al., 2020; Tomaszewski et al., 2014; Vrijens et al., 2017) Improving how antihypertensive medications are used has the potential to quickly reduce BP and the related cardiovascular risk in most patients (McEvoy et al., 2024). When considered as a behaviour, medication-taking can be broadly broken into three components: initiation (which occurs when a person takes the first dose of the prescribed medication); implementation (the extent a patient's actual dosing corresponds with the prescribed regime); and discontinuation (which occurs when the patient stops taking the medication) (Vrijens et al., 2012). A term related to these behaviours is persistence, which refers to the length of time between initiation and last dose (Vrijens et al., 2012). A number of interventions have been implemented to improve medication-taking behaviours in hypertension, and, while these have generally shown modest improvements, there is no consensus on what intervention 'ingredients' are most effective (Morrissey et al., 2017).

Inertia is the second key challenge identified in global blood pressure control (McEvoy et al., 2024). Clinical inertia is largely seen as failure to advance therapy when appropriate to do so, an issue that is particularly pertinent in the treatment of hypertension. Two Irish studies have confirmed that suboptimal dosing is a significant issue in Irish general practice populations of patients with resistant hypertension (Hayes et al., 2018) and post stroke and/or transient ischaemic attack (Doogue et al., 2020). However, in terms of the definition of 'clinical inertia,' it can be argued that failure to advance therapy is just one feature of a larger phenomenon. It has been suggested that 'clinical inertia' is not only related to escalation of therapy, but is a much wider concept which encompasses failure to improve care at many levels of healthcare (Khunti & Davies, 2017). In the context of hypertension care, we know that conversations around medication-taking behaviour are often omitted – a recent survey of 200 hypertension specialists in 30 countries found that the topic of medication-taking was suboptimally addressed, despite its importance (Burnier et al., 2021). A similar survey of healthcare professionals

($n = 3196$) working in primary care in Europe found that less than half of respondents ever asked their patients whether they have missed any doses of their medication (Clyne et al., 2016).

This avoidance of this topic in the patient-physician consultation may represent a 'missing piece' in the medication-taking puzzle, as it is well established that primary care clinicians can enable patients in their medication-taking practices (Chen et al., 2013; Kerse et al., 2004). A supportive discussion can identify which perceptual and practical barriers a patient may be facing in their medication taking. For example, a recent phenomenological hermeneutical study on patients with cardiac conditions' experiences with medicines reported the theme of 'unsuitable without adjustment.' This qualitative data highlighted how discussion with the prescribing physician and changes to both the type and dose of medication may be required to make medication suitable to the patients' lives (Fuller et al., 2021). Therefore, a systematically developed approach is needed to ensure that the hypertension consultation includes the topic of medication taking. This will help avoid that part of clinical inertia that is associated with assessing patient barriers and facilitators to medication taking and providing appropriate supports for long-term medication use.

A key objective of the present study was to develop a complex intervention that would support both General Practitioners (GPs) and people with hypertension to maximise medication use to control blood pressure. The field of complex intervention development has benefitted from recent advances in guidance, such as the updated Medical Research Council (MRC) framework (Skivington et al., 2021) and O'Cathain's consensus exercise (O'Cathain et al., 2019). Both emphasise the importance of reviewing the evidence, drawing on existing theories, using development frameworks (such as the Behaviour Change Wheel, Michie et al., 2011), articulating programme theory, understanding context and involving stakeholders throughout the iterative development process.

To generate the evidence required for the intervention development, we conducted two systematic reviews and three primary studies; this work is outlined in Table 1. We also set up a 'Public and Patient Involvement' (PPI) panel of six people with lived experience of hypertension and primary care to guide the work.

We selected the three-phase Behaviour Change Wheel (BCW) as the development framework for this work and used our evidence sources, relevant theory (Horne et al., 2019; Horne & Weinman, 1999) and PPI input to complete Phase 1, which involves identifying components of the target behaviour (who, what, where, when, and how often) to be addressed through the intervention using the COM-B (Capability, Opportunity, Motivation-Behaviour) model. Table 2 outlines the breakdown of the target behaviours and mapping of the target 'modifiable factors.'

Phases 2 and 3 of the BCW are 'identifying intervention options' and 'identifying content and implementation options.'

Some intervention options were integrated into existing hypertension management protocols in the Irish context. For example, Ambulatory Blood Pressure Monitoring (ABPM), is recommended as a key part of the diagnosis and the ongoing management of blood pressure in primary care in Ireland and many other contexts internationally (Cepeda et al., 2023). Therefore, the intervention was embedded within general practice sites' existing ABPM protocols. We also supplemented the ABPM protocol with a chemical adherence test that was carried out on patient urine samples provided around the time

Table 1. Evidence sources used in the development phase of the MIAMI intervention.

Source	Type of activity	Overview of findings	BCW step(s) informed
Prevalence of treatment-resistant hypertension after considering pseudo-resistance and morbidity: A cross-sectional study in Irish primary care (Hayes et al., 2018)	Primary cross-sectional research	• Aimed to describe the prevalence of apparent treatment-resistant hypertension in general practice in Ireland. • Reviewing individual general practice patient records ($n = 50,174$) resulted in a lower estimate of the prevalence of treatment resistant hypertension than has generally been previously reported. • For individual patients consideration of additional criteria such as morbidity, dosing, exclusion of white coat hypertension, and adherence lowers these estimates even more. This suggests that treatment resistant hypertension is an uncommon condition in general practice and **use of ABPM, adequate dosing, and maximising adherence may be all that is required to manage the vast majority of cases**.	1, 2
Medication adherence among patients with apparent treatment-resistant hypertension: Systematic review and meta-analysis (Durand et al., 2017)	Systematic review	• Aimed to describe the prevalence and potential moderators of medication non-adherence estimates for apparent treatment-resistant hypertension • 24 studies included and pooled prevalence of non-adherence was 31.2% (95% CI [20.2, 44.7], $I^2 = 99.50$) with non-adherence rates ranging from 3.3–86.1%. • **Findings indicate that medication non-adherence is a significant problem among people with apparent treatment resistant hypertension**	1, 2
Medication adherence for resistant hypertension: Assessing theoretical predictors of adherence using direct and indirect adherence measures (Durand et al., 2018)	Primary cross-sectional research	• Aimed to identify theoretical predictors of long-term medication adherence for patients with apparent treatment-resistant hypertension in general practice. • Patients ($n = 204$) completed two self-report adherence measures and **urine testing used as an objective measure of adherence** • Medication-taking habit strength was the strongest predictor of adherence, explaining 19% incremental variance in adherence beyond treatment-related beliefs. • Associations among unique adherence measures were weak overall, providing further evidence that multiple measures are necessary to accurately assess adherence. • **Habit strength and pill burden represent important intervention targets for improving long-term medication adherence.**	3, 4, 5

A qualitative comparison of high and low adherers with apparent treatment-resistant hypertension (Durand et al, 2020)	Primary qualitative research	• Aimed to investigate factors associated with good and poor adherence in patients with apparent treatment resistant hypertension in primary care. • Patients ($n = 14$) who self-reported both high and low adherence in a previous quantitative study were purposively sampled. • Three themes were identified, beliefs about treatment, habits and routine, and health and health systems • High adherers reported favourable beliefs about antihypertensive treatment that had been validated by experience with treatment over time, **described strong medication-taking habits and stable routines, and positive relations with their GP** • Low adherers expressed less coherence of beliefs and used less successful strategies to support medication-taking in daily life	3, 4, 5
Effectiveness and content analysis of interventions to enhance medication adherence and blood pressure control in hypertension: A systematic review and meta-analysis (Morrissey et al., 2017)	Systematic review	• Aimed to evaluate the effectiveness of medication adherence interventions on blood pressure control in people living with hypertension. • 26 studies included and **meta-analysis of interventions documented significant but modest post-intervention improvements in BP outcomes among people with hypertension.** • However, this is a tentative finding as substantial heterogeneity and potential biases were present. • It is imperative that future adherence research comprehensively reports methodology.	5, 7, 8
PPI meetings	PPI meetings	• Aimed to provide insight and information about the intervention context from a patient perspective. • Aimed to get expert input and guidance into the intervention development, particularly around the operationalisation and mode of delivery of intervention components.	1, 2, 3, 4, 5, 7, 8

Table 2. Phase 1 of the Behaviour Change Wheel.

Medication taking	
Target behaviour	
Who	Person with hypertension
What	Taking medication as prescribed
When, where, how often	As part of daily routine
Target factor	COM-B component
Treatment beliefs	Reflective motivation
Habit	Automatic motivation
Pill burden	Physical opportunity
Inertia	
Target behaviour	
Who	GP
What	(1) regularly reviewing a patient's anti-hypertensive medication to ensure the optimal dosing (2) opening conversation about medication use with patients (3) provide medication-taking supports to patients
When, where, how often	As part of regular practice
Target factor	COM-B component
Familiarisation with dosing guidelines	Psychological capability
Capacity (and time) to have conversations about medication use	Social opportunity
Competing priorities in consultation	Reflective motivation
Familiarisation with medication-taking supports	Psychological capability

of ABPM administration. Chemical adherence testing is an emerging assessment procedure that screens for the presence of medications in patient urine samples (Lane et al., 2022). There is some evidence that this test can facilitate patient and provider conversations about medication that might help improve adherence to antihypertensives and reduce BP (Gupta et al., 2017).

Stakeholder involvement is a critical component of Phases 2 and 3 of the BCW. In this context, 'Collective Intelligence' is a useful method for systematically operationalising stakeholder engagement. The term Collective Intelligence refers to the intelligence, or knowledge, that is generated from a group of people working together on a complex problem. The process of Collective Intelligence carefully delineates content and process roles. Responsibility for contributing ideas is assigned to experts, while the workshop facilitator takes responsibility for choosing and implementing selected methodologies. The methodologies are carefully selected for key tasks, including generating, clarifying, structuring, interpreting, and amending ideas. Emphasis is given to balancing behavioural and technical demands of group work while honouring design laws concerning variety, parsimony, and saliency (Broome & Chen, 1992). There must be enough variety in options to cover all needs, but possible paths and solutions must exist in harmony to avoid creating confusion or disrupting problem resolution (Klir & Ashby, 1991). In the context of interdisciplinary work, Collective Intelligence supports high quality idea generation and exchanges, as it includes a set of methods, tools, and a facilitated thought and action mapping process that helps groups to develop outcomes that integrate contributions from individuals with diverse views, backgrounds, and perspectives (Hogan et al., 2014). Collective Intelligence has been applied in a wide variety of situations to accomplish many different goals including developing a national well-being measurement framework (Hogan et al., 2015), designing an e-learning tool to

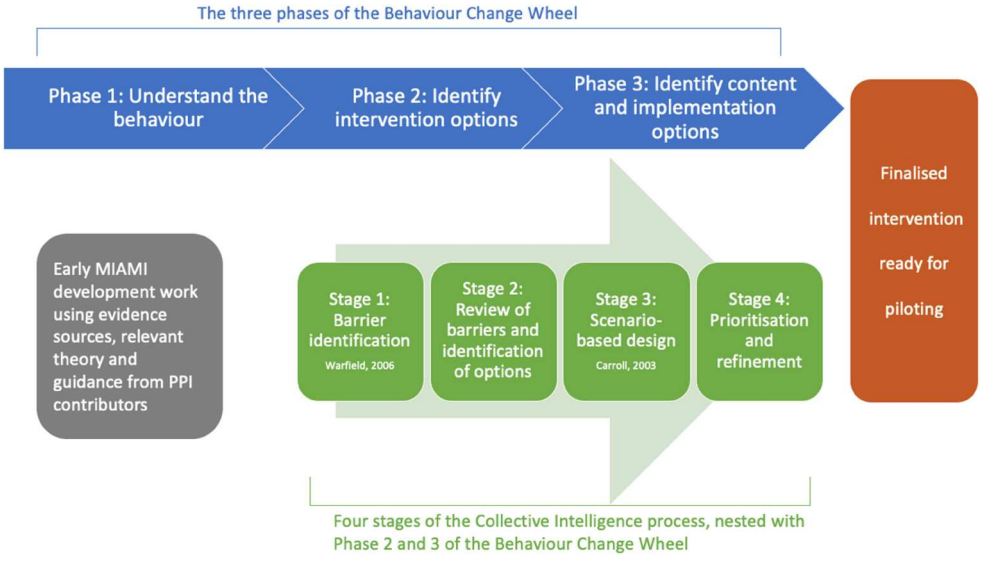

Figure 1. The Collective Intelligence process nested within the overarching BCW framework (Carroll, 2003; Warfield, 2006).

support health practitioners caring for patients taking multiple medications (Hanlon et al., 2020) and identifying barriers and user needs from eHealth interventions for chronic pain (O'Reilly et al., 2022). Figure 1 illustrates the Collective Intelligence process nested within the BCW. The Collective Intelligence method is particularly compatible with the BCW emphasis on placing 'no priority on an individual, group, or environmental perspective – intra-psychic and external factors all have equal status in controlling behaviour' (Michie et al., 2011)· Collective Intelligence explicitly assigns equal expert status to all stakeholders including patients, clinicians and behaviour change specialists; in identifying content and implementation options.

This paper describes the systematic development of a complex intervention to support General Practitioners (GPs) and people with hypertension to maximise medication use to control BP, i.e. the MIAMI intervention. We particularly focus on the role of Collective Intelligence in informing Phase 2 and Phase 3 of the BCW approach to intervention development. This MIAMI intervention is currently being evaluated in a pilot cluster randomised controlled trial (RCT) that aims is to gather and analyse feasibility data to allow us to (1) refine the intervention, and (2) determine the feasibility of a definitive RCT. The full protocol has already been published (Morrissey et al., 2023).

Method

The development process is reported using the Guidance for Reporting of Intervention Development (GUIDED) checklist (Duncan et al., 2020) (see Appendix 1) and the intervention is reported using the Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann et al., 2014) (Appendix 2).

Ethics

Ethical approval was granted from the Irish College of General Practitioners Research Ethics Committee (ICGP_REC_21_0050).

Participants

Nineteen stakeholders, with a variety of expertise, including lived experience, general practice, nursing, pharmacy and health psychology took part in the Collective Intelligence workshop. Table 3 outlines the backgrounds of participants. Patient representatives (people living with hypertension) were invited from the project PPI panel, as well as an open invitation in a local newspaper. The remaining participants were invited purposively to ensure diversity in backgrounds and perspectives. The workshop took place in April 2022 at the University of Galway. Informed consent was obtained from all participants.

Procedure

Stage 1: pre-workshop idea generation

The first stage of the Collective Intelligence process involved systematic analysis of barriers to meaningful and productive dialogue between patients and GPs around medication use in the context of hypertension. The 19 stakeholders were contacted in advance of the session by email, with a request to generate a set of barriers in response to the following trigger question: 'What are barriers to patients and GPs bringing up and working through issues around how people with high blood pressure use their medication?' By email submission, stakeholders identified 154 barriers. These responses were subsequently reviewed by the research team and categorised using the paired comparison method (Warfield & Cárdenas, 1994). The paired comparison method provides a simple way of summarising a group of individuals' opinions, attitudes or beliefs about a

Table 3. Participant characteristics.

Participant number	Background and expertise	Gender
1	Patient representative (MIAMI PPI panel member)	Man
2	Patient representative (MIAMI PPI panel member)	Man
3	Patient representative (MIAMI PPI panel member)	Man
4	Patient representative (MIAMI PPI panel member)	Woman
5	Patient representative (MIAMI PPI panel member)	Woman
6	Patient representative	Man
7	Patient representative	Man
8	Patient representative	Woman
9	Clinical pharmacologist	Man
10	GP and researcher in primary care	Man
11	GP and researcher in primary care	Man
12	GP	Man
13	GP trainee	Man
14	Nurse (primary care)	Woman
15	Research nurse in primary care	Woman
16	Dietician	Woman
17	Pharmacist	Woman
18	Researcher in health psychology	Woman
19	Researcher in health psychology	Woman

topic in a systematic and objective manner. Responses are clustered into categories, based on conceptual similarity, so that they can be presented back to the group as an overview of the issues within each category, and the problem space as a whole. These categories provide a focus for initial discussions at the Collective Intelligence workshop.

Stage 2: review of barriers

On the day of the Collective Intelligence workshop, the workspace was arranged such that the 'problem field' (i.e. the categorised barriers received in advance of the session) were displayed on the walls. Participants were deliberately divided into four groups prior to the workshop, with a mix of stakeholder expertise and perspectives at each table. The workshop was facilitated by two experts in Collective Intelligence, who were not part of the project team. A short presentation providing an overview of the problem space as regards hypertension and medication was delivered to provide context for the activities that would be completed throughout the day.

Following the presentation, participants engaged in a review of the categories of barriers, with a view to generating options for overcoming these barriers. To generate options in response to barriers, small working groups of participants (4–5 persons each) engaged in idea generation in response to three assigned barrier categories. During this stage of the workshop, the 'ideawriting' technique was used (Wood & Roth, 1990). Each of the small working groups was asked to generate options in writing and to use open dialogue to explore the meaning of ideas generated. Five steps were involved in idea writing: (a) a stimulus question was presented to participants; (b) each participant worked alone to silently generate ideas in writing; (c) written sheets of ideas were exchanged within the working groups and individuals had the opportunity to add ideas as they read others' papers; (d) unique ideas were discussed and clarified; and (e) each working group orally reported the ideas generated in a plenary session. This stage of work focused on the generation of options in response to barrier categories and allowed stakeholders to scope out a broad range of options in response to barriers before focusing attention on specific scenarios of application of the MIAMI intervention.

Stage 3: generation of user needs

The next stage involved using scenario-based design methods to generate specific user needs (Rosson & Carroll, 2002). In advance of the Collective Intelligence session, the research team and facilitation team worked together to design a set of scenarios that could be used as inspiration for group idea generation during the workshop. These were based on relevant theories and frameworks (e.g. the Common-Sense Self-Regulation Model Leventhal et al., 2003 and Necessity-Concerns Framework Horne & Weinman, 1999), the work the research team had conducted on Stage 1 of the BCW (see Table 2) and clinical experience. Following guidelines provided by Rosson & Carroll (Rosson & Carroll, 2002), design representations captured in the scenarios were concrete, flexible, and generative and did not specify fixed solutions. The scenarios that were designed by the facilitation and research team for this task presented challenges faced by both GPs and patients, to help workshop participants to orient themselves in each individual 'actor's' problem space, so that they could imagine such a situation arising and consider what supports would be useful in each of these circumstances.

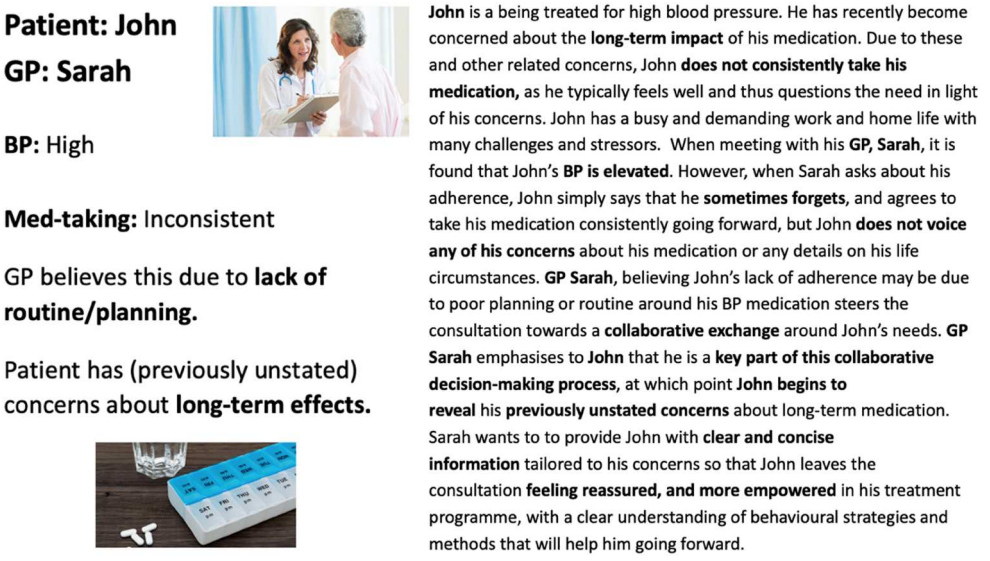

Figure 2. Scenario used in Stage 3.

An example of one of the scenarios used can be seen in Figure 2. The aim was to prompt user needs in relation to: (1) Information Needs; (2) Communication Needs; (3) Decision-Making Support; and, (4) Behavioural Support Needs. Participants were asked to consider the roles of each actor in each scenario and generate a list of needs, and the reasons for these needs. These needs were subsequently discussed by sub-groups and all ideas were collated by the workshop facilitation team. The identification of user needs generated through this scenario-based design stage, informed by the earlier Collective Intelligence analysis of barriers, and generation of targeted options, provided a strong basis for further design work.

Stage 4: prioritisation and refinement

As outlined in the introduction, the Collective Intelligence process was couched within the larger framework of the BCW. The targeted options produced at the Collective Intelligence workshop allowed us to identify possible intervention functions (Phase 2 of the BCW) but refinement, identification of content and operationalisation was required (Phase 3 of the BCW). This was conducted by the core research team and PPI panel. User needs and targeted options were tabulated by the research team and brought to PPI and wider study team meetings, where the priority of each need and utility of each option was discussed. This was informed by the Acceptability, Practicability, Effectiveness, Affordability, Side-effects and Equity (APEASE) criteria (Michie et al., 2011). If an option met the APEASE criteria and was considered acceptable and useful, it was chosen as an intervention component. Components were mapped to the intervention functions of the BCW and Behaviour Change Technique Ontology to inform the logic model of the intervention. Subsequent meetings focused on possible barriers and suggestions for improvement to each component. Several iterations of each component were worked through until the component was considered acceptable and useful to PPI panel members.

Results

Stages 1 & 2: pre-workshop idea generation and review of barriers

In response to the pre-workshop idea generation, 154 barriers to patients and GPs bringing up and working through issues around how people with high blood pressure use their medication were collated. Using the paired comparison method, these were summarised across 15 categories.

During the workshop, stakeholders generated a total of 157 options for overcoming these barriers. Table 4 presents an overview of the categories, sample barriers, and sample options for overcoming barriers. The full categorised sets of barriers and options can be found at https://osf.io/xusby/

Stage 3: generation of user needs

Using scenario-based design, stakeholders also identified a set of user needs, under the four headings of (i) information needs, (ii) communication and collaboration needs, (iii) decision-making needs, and (iv) behavioural support needs.

Stakeholders identified 102 *Information Needs* (subsequently divided into 10 categories), 126 *Communication and collaboration needs* (subsequently divided into 8 categories), 65 *Decision-making needs* (subsequently divided into 6 categories) and 89 *Behavioural support needs* (subsequently divided into 8 categories). Table 5 provides the five most common needs within each category, along with a selection of illustrative quotes. The full set of categorised needs is provided at https://osf.io/xusby/

Stage 4: prioritisation and refinement

Through the use of the APEASE criteria, along with discussion with the PPI panel and wider research team, user needs were prioritised and targeted options were chosen to become intervention components. These were mapped to the intervention functions of the BCW and Behavioural Change Technique Ontology (Marques et al., 2023). The research team and PPI panel then worked together to operationalise and create the content for the intervention components. For example, the informational BP videos were co-created by the research team and PPI panel, where the PPI panel suggested content for the video, the research team drafted the video and the PPI panel gave several rounds of feedback with suggested modifications before approving the final version.

The finalised MIAMI intervention is described in Table 6. The logic model for the intervention is depicted in Figure 3, to graphically represent the intervention structures and processes, including proposed BCTs and associated mechanisms of action. Intervention components can be seen in detail in the intervention manual (https://osf.io/xusby/).

The TIDieR checklist is presented in Appendix 2.

Discussion

This paper comprehensively and transparently reports the development process of the MIAMI intervention, with the BCW as an overarching guidance framework and

Table 4. Results of Stage 1 and Stage 2 of the Collective Intelligence process.

Name and description of barrier	Examples of barrier	Example of options
Understanding Barriers relating to issues of knowledge, awareness, and understanding of patients in relation to medication for high blood pressure	• Difficulties in understanding their medication regime. • Inability to understand prescribing details. • Challenges associated with language barrier. • Failure of practitioners to use plain language when describing key concepts and instructions.	• At initial consult (before the patient starts medication) GP could outline possible side effects/what to expect and how to minimise them e.g. stand up slowly so BP does not drop, take with food. • GP could provide an explanation of what high blood pressure is, the impact it can have if left untreated and why medication is needed in this particular instance/for this patient in particular • Use/signpost existing sources which will be regularly updated, e.g. Croí/Irish Heart Foundation (provide these)
Perceived necessity Barriers associated with the extent to which patients believe blood pressure medication to be necessary and important, or not	• Patients not believing the consequences of skipping medication are severe. • Patients believing that blood pressure medication is less important than other medication. • Patients' belief that they should feel symptoms if they have high blood pressure and lack of symptoms means they question need for medicines. • Challenge of getting patients to come back for checks, i.e. blood pressure (BP) and convincing patients of the importance of keeping BP in within range.	• GP could ask patient to arrange to make an appointment for X amount of weeks before they leave the surgery, rather than saying to ring to make it • GP could briefly summarise why the BP is as needed as other medications in order to maintain overall health and management of other conditions they may have. Direct patient to HSE, Croí, Irish Heart Foundation to get additional knowledge
Patient supports The absence of supports for patients who need to take medication for high blood pressure	• Lack of support to prompt taking medicines correctly. • Lack of supports for elderly patients living alone. • Lack of networks or social supports to assist individuals with complex healthcare decisions.	• App prompt on phone, e.g. dontforget.ie • GP/Nurse could arrange blister packs with the patient's pharmacist to make it easier for the patient to know when they have taken their daily tablet. • Nurse could arrange phone call to discuss side-effects and suggestions for taking the medication, (e.g. with food/before bed) etc. and arrange to call back after X amount of weeks to check in.
Negative beliefs about medication Barriers relating to patient's concerns and fears about medication	• The belief that less medication is better for overall health. • Concerns that the side effects will be greater than any benefit. • Interference from external sources of misinformation.	• Establish a plan with patient regarding dose/timeframe. Agree in the plan a timeframe for review and develop personal action plan. • Establish/ascertain basis for negative beliefs and target that – ask what the concerns are? If it is side-effects, ask would it be helpful to talk through these and make a plan. • Reassure that medication options are always available and importance of finding 'right medication.' • Acknowledgement of range of information on the internet and reinforcement of importance of using scientific information provided by healthcare professionals (national campaign, not just one-to-one).

Resistance to diagnosis and treatment Beliefs and concerns that patients have in relation to receiving a diagnosis of, and beginning treatment for, high blood pressure.	• A fear that taking medication for one condition is just the beginning of needing medication for many conditions. • Resistance to discussing long-term outcomes of uncontrolled blood pressure. • An unwillingness to accept that the risk of stroke is high but will be lessened by medication.	• Promote the idea that taking BP meds now will prevent future illness and more medication. • Support a trial of lifestyle change before starting medicines, e.g. 6 months diet and physical activity then review again.
Personal circumstances and challenges Barriers addressed a range of external factors which can impinge on an individual's ability to consistently take their blood pressure medication.	• Difficulties relating to accommodation, with examples given of patient's living in shared or temporary accommodation. • Challenges associated with family or caring commitments. • Irregular work schedules. • Cognitive or memory difficulties.	• Easy to open blister packing from the pharmacy – helps with timing, remembering, and organising meds. • Address underlying causes of difficulties – referral to social worker, addictions counsellor, etc.
GP assumptions Challenges specifically from the GP side of the interaction, such as false beliefs and assumptions.	• The belief that is it the responsibility of the pharmacist to discuss medication instructions and adherence. • The assumption that patient are generally happy to take their medication as prescribed. • The belief that if a patient takes their medication for one condition, then they will do so for any other conditions.	• Prompt checking of patient's understanding and knowledge with a template generated in GP computer software. • Recommend that GP encourages dialogue about any specific patient concerns re medications.
Dialogue and decision making Challenges relating to poor conversational dynamics which may impact on a patient's decisions around their medication.	• An inability to engage in these conversations in a non-confrontational way, • A failure to elicit any concerns the patient may have. • Concern that the patient may not respond well to being asked about their adherence. • Fear of damaging the relationship.	• Have refresher training programmes for GPs on how best to have a difficult conversation without anyone becoming uncomfortable. • Encourage and promote involvement of practice team, especially practice nurses – patients will often discuss things in more detail with practice nurse. • GP to give extra time to patient when she suspects non-adherence.
Multimorbidity Challenges faced by patients in managing multiple conditions and prescriptions.	• Flare-ups in other conditions can disrupt a patient's daily routine, including their medication taking. • Stakeholders also addressed multimorbidity barriers in the context of consultations, as discussions of other conditions can result in little to no time remaining to discuss blood pressure medication.	• Develop an 'action plan' for GPs so that regardless of number of conditions, each one gets appropriate priority time and attention. • Develop procedure for GPs to always take BP measurement at start of consultation and ensure BP management is included in discussion.

(*Continued*)

Table 4. Continued.

Name and description of barrier	Examples of barrier	Example of options
GP prescribing worries Fears and concerns that GPs have in relation to prescribing blood pressure medication.	• Concerns about potential negative consequences of these prescriptions, including concerns of inducing low blood pressure or causing falls in older patients, fears of side effects or renal deterioration, and fears associated with white coat hypertension.	• No options generated
GP consultation constraints Barriers associated with the lack of time available for consultations, and the range of negative implications this lack of time has.	• Shortage of time to build a strong relationship between GP and patient. • Lack of time to adequately discuss medication and adherence behaviours. • Concern that opening such a conversation, under time constraints, could result in a long discussion and a complete change in several medications.	• Create a practice handout to give all patients on BP meds outlining importance, tips, adherence issue checklist; e.g. price, hesitation to take meds. • Encourage patient to arrive to appointment with list of medication concerns if they have any. • Develop a shared agreement on what matters are important to both pt. and HCP – review continuously.
Routines and habits Barriers which impinge on patient's ability to form habits and consistently take their medication.	• Changes in an individual's daily routine due to vacation. • Unpredictable working hours, or changes in the home. • Challenges associated with integrating the medication rules schedule into their daily routine (e.g. take 30 min before food). • Failure to carry medication when away from the home for long periods of the day.	• Develop an action plan with cues to take medications e.g. with toothbrush, at kettle, beside bed. • Provide a portable pill box that can be easily carried if leaving home for work, vacation, etc.
Perceived power imbalance Patients' reluctance to engage in this discussion, or disclose their concerns, out of fear of being judged negatively by the GP.	• Patients' belief that would be in trouble for not taking their medication. • Belief that the GP will consider their concerns to be foolish. • Concerns that the GP will no longer help them if they admit to not taking their medication. • Belief that the GP won't fully explain the side-effects to them.	• Provide examples of legitimate reasons someone may not be adherent, so patients feel comfortable being honest about their reasons. • Identify another HCP who can address medication concerns, e.g. practice-based pharmacist or nurse – who has (and is seen to have) time and is not a stakeholder in prescribing.
Cost A stand-alone category of barriers, negatively impacting on open conversations between GPs and patients in relation to taking blood pressure medication.	• Cost can be an unstated concern, whereby patients do not disclose the true reason for not wanting to be prescribed medication, especially long-term medication. • Conflict between needing the medication, and the cost of the GP visit in the first place.	• GP could provide leaflets in the surgery about drug payment scheme, etc.
Planning and organisation Challenges with planning skills.	• Difficulties in planning (e.g. ordering and collecting repeat prescriptions before supply runs out).	• No options generated.

Table 5. Results of stage 3 of the Collective Intelligence process.

Categories of needs	Sample needs within the consultation
Information needs	
Patient understanding (22%)	'To understand why I need medication'
Importance of controlling blood pressure (17%)	'Information on the consequences of not taking the medication'
Forms of information delivery (13%)	'Written information to take home with me'
	'An infographic to explain the risks and side effects'
Understanding the patient perspective and concerns (13%)	'To know what concerns, worries the patient has with taking all of her medication'
	'Information about the best way to support patient decision making'
Accessibility and quality of information (9%)	'Easy access to leaflets, website and videos that can be recommended to patients'
	'Clear and concise instructions about my tablet'
Communication needs	
Empowering and understanding (27%)	'GP to acknowledge my difficulties'
	'An action plan that reflects my needs + expectations, tailored to me/my lifestyle'
	'To be an active participant in my options'
Open communication (24%)	'Ask open questions around medication taking'
	'Open, honest, person centred communication'
	'To practice using clear language'
Creating an environment for communication (24%)	'To avoid seeming rude or dismissive'
	'Need the patient to feel that the decisions are collaborative'
Tools and strategies (6%)	'To use tools to determine patient's needs'
	'Have a pre-consultation plan, so can have questions/concerns ready to discuss'
Communication actors (6%)	'Involve the practice nurse in communication'
	'My GP to send the pharmacist my prescription directly'
Decision making needs	
Shared decision making (34%)	'Ask patient if she agrees with decision'
	'Actively listen to each other'
	'To balance my professional opinion with the desires of the patient'
Informed decision making (23%)	'To ensure that patient has the information necessary to make an informed decision'
	'Think about what I want from the doctor appointment'
	'My GP to provide recommended resources e.g. websites/online apps'
Tools to support decision making (17%)	'A list of prompts to guide my conversation – focused but open'
	'A tool I can take home with me so that I can reflect and affirm my decision making'
Plans and expectations (14%)	'Decide what is most important to work out first'
	'At the appointment close, ask 'so are you happy to try that?'
	'An agreement on follow up plans'
Testing (6%)	'The inclusion of the urine testing to be clear and safe'
	'Further tests – 24 h blood pressure monitor'
Behavioural support needs	
Tools and strategies (34%)	'Offer some tools to remind the patient to take meds'
	'A app or test messaging service assist with reminders'
Support from others (17%)	'To know of and be able to direct and signpost the patient to community/online supports (groups/information/class)'
	'An easy way to communicate with pharmacists re. supporting patients'
	'Talk to my family about my medicine needs'
Follow-up (11%)	'To follow up regularly with the patient'
	'To schedule a follow-up appointment to check on my progress and for support'
Goals and roadmaps (10%)	'Agree a roadmap of actions with the patient'
	'To be clear on what exactly I have to do'
Medication and lifestyle (10%)	'Link medication-taking with other habits'

Collective Intelligence methodology used to operationalise stakeholder input. GUIDED and TiDIER checklists can be seen in Appendices 1 and 2. The finalised intervention provides supports to both GPs and people with hypertension to allow a useful and

non-judgemental consultation about medication-taking. Full details of GP and patient components can be seen in Table 6.

One of the particularly novel aspects of this behavioural intervention was the use of the chemical adherence test as part of this complex behavioural intervention. There is increasing interest in using such tests as part of hypertension care (Lane et al., 2022); we have previously shown, in a pilot study, the feasibility, acceptability, and efficacy of routinely using these tests in Irish general practice (Hayes et al., 2019). There is

Table 6. Finalised MIAMI intervention.

		GP	
Component	User need	Intervention function	Details
Training videos	Communication need Information need Behavioural need	Education Training Modelling	30 min training package(6 short videos and quiz) Part 1: Adherence to medication, including the extent of non-adherence, key factors associated with adherence, and types of non-adherence Part 2: Three case studies to illustrate how you might support patients' medication adherence in different scenarios Part 3: Skills and strategies to support adherence Part 4: A case study illustrating the use of the MIAMI intervention
MIAMI booklet	Information need	Education	Booklet contains • BP thresholds (American College of Cardiology) • Oral anti-hypertensive drugs (American College of Cardiology) • Core drug treatment strategy for uncomplicated hypertension (European College of Cardiology) • List of available single pill combinations • Simple reiteration of key training messages
Drop-down menu on computer to guide consultation	Communication need Decision need Behavioural need	Environmental restructuring	Drop-down menu on computer which contains a guide to the consultation. • Discussed ABPM YES/NO • Discussed urine results YES/NO • Made an agreed plan which may include: single pill combinations, 'blister pack' specification: YES/NO • Asked patient to form a habit (pair medication taking with another stable behaviour e.g. a mealtime/brushing teeth/ Coronation Street): YES/NO • Wrote out the agreed plan on the 'MIAMI pre-consultation tool' YES/NO • Sent relevant text message: YES/NO Text to copy and paste into text messages You can set up text messages to remind you to take your medication at dontforget.ie Information about blood pressure and blood pressure medication is available on the Croí website: https://croi.ie/health/heart-conditions/high-blood-pressure/

Table 6. Continued

Patient			
Component	User need	Intervention function	Details
Pre-consultation plan	Communication need Decision need	Environmental restructuring	Short document containing • 'What do you want to talk about at your blood pressure appointment today?' (to be filled in prior to consultation) • Textbox for BP reading and whether it is in target • Textbox for goal setting and action planning (to be used during consultation)
GP consultation	Communication need Decision need Behavioural need	Environmental restructuring	Discussion of ABPM and urine test results. Use of pre-consultation plan to create shared action plan GP to review prescription and adjust to include single pill combinations and blister pack if appropriate GP to advise on habit creation GP to send text messages on dontforget.ie and Croí website if appropriate
Croí website	Information need	Education	Page on website containing (both text and video format) • information on BP • BP values • how medication works • benefits of medication • possible side effects

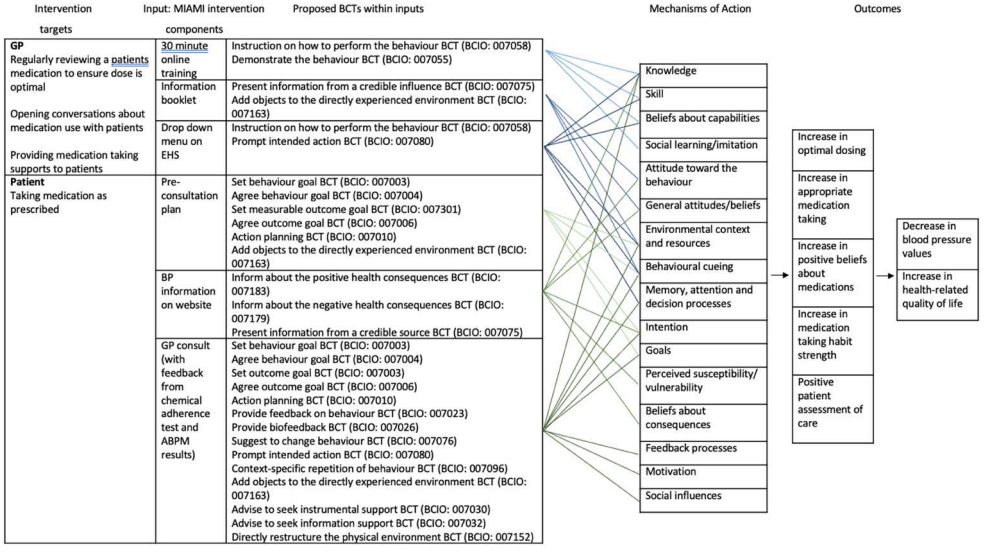

Figure 3. MIAMI logic model.

similar confirmatory evidence from a UK opportunistic study of 191 patients with hypertension, all on at least one blood pressure lowering medication, that it is indeed feasible to carry these tests out in a general practice setting. However, this UK study suggested that it is not appropriate to carry out these tests routinely given the low prevalence of 4.7% of chemical non-adherence that was detected (mean age 76.2 ± 6.6 years) (Sheppard et al., 2022). The authors recommended that chemical urine testing be reserved for patients

who are on multiple blood pressure lowering medications and whose blood pressure control is not optimal. This is the specific patient group for which the MIAMI intervention has been developed (Lane et al., 2022).

Another unique feature of this study was the use of the Collective Intelligence methodology within the BCW framework for behavioural intervention design. This provided an efficient method to collectively orient and engage a diverse group of stakeholders in this complex problem space. However, the BCW focuses on identifying and changing one specific behaviour and following a prescribed set of steps to identify intervention options. It was sometimes challenging to maintain this approach in the intervention development process, given the complexity of the multiple interdependent patient and provider behaviours involved in using medication appropriately. While Collective Intelligence provides a systematic and structured method to gather input from multiple stakeholders, it also provided the freedom to reconceptualise the nature of the problem and to generate solutions that are not easily rendered into specific techniques and related mechanisms of action. For example, the identification of the critical role of enhancing the more intangible 'space between us' factors (Lloyd, 2009) that might be variously referred to as therapeutic alliance (Elvins & Green, 2008) or patient-provider relationship (Drossman & Ruddy, 2020) meant that reducing the solutions to a set of specific behaviour change techniques and related mechanisms of action was challenging at time. While we do believe that Collective Intelligence aligns with the spirit of the BCW and PPI in research, in that it assigns equal expert status to all stakeholders including patients, clinicians and behaviour change specialists, it remains to be seen whether this method translates more widely to multiple health behaviour change design applications.

A key question that this study can address relates to the feasibility of addressing one specific kind of medication use for one single disease, as part of a behavioural intervention in a general practice consultation. Recently the powerful concept of Time Needed to Treat (TNT) has been developed (Johansson et al., 2023). Broadly speaking this refers to the time in a consultation that would be required to implement a treatment recommendation and serves to remind those developing interventions and guidelines for the general practice context that implementation of new disease-specific practices might often be unfeasible, if time constraints are not appropriately considered (Albarqouni et al., 2023). This is particularly the case given the reality of the extent of multimorbidity and related polypharmacy in older adulthood, where GPs are often faced with an already unmanageable range of guideline recommended practices to prioritise before patient support with medication-taking can be considered (Foley et al., 2021). By working closely with GPs throughout the project, the evaluation of the MIAMI intervention will keep these implementation considerations at the forefront of the final analyses.

In conclusion, there are several strengths to this intervention design, including the systematic development of the intervention, the diverse stakeholder involvement, and continuous PPI contributions throughout the entire programme of work. While this was sometimes challenging, it allowed the behavioural intervention development to align with the principles of co-production that are increasingly recognised as being essential to the design of sustainable and implementable health interventions (Batalden et al., 2016). The detailed description of the intervention development and content in this paper will enable future work to incorporate the study findings more accurately into evidence synthesis research and to carry out replication studies or extensions and

refinements of the MIAMI intervention. The full pilot and feasibility evaluation of the MIAMI intervention, including a qualitative substudy and health economics costings, is underway and will be reported separately in a subsequent paper.

Open Scholarship

This article has earned the Center for Open Science badge for Open Data. The data are openly accessible at https://osf.io/xusby/.

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Data availability statement

The materials and datasets generated and/or analysed during the current study are available in the OSF repository https://osf.io/xusby/.

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Appendices

Appendix 1. GUIDED checklist

Item description	Explanation	Page in manuscript
1. Report the context for which the intervention was developed.	Understanding the context in which an intervention was developed informs readers about the suitability and transferability of the intervention to the context in which they are considering evaluating, adapting or using the intervention. Context here can include place, organisational and wider sociopolitical factors that may influence the development and/or delivery of the intervention	2,3
2. Report the purpose of the intervention development process.	Clearly describing the purpose of the intervention specifies what it sets out to achieve. The purpose may be informed by research priorities, for example those identified in systematic reviews, evidence gaps set out in practice guidance such as The National Institute for Health and Care Excellence or specific prioritisation exercises such as those undertaken with patients and practitioners through the James Lind Alliance.	2,3
3. Report the target population for the intervention development process.	The target population is the population that will potentially benefit from the intervention – this may include patients, clinicians, and/or members of the public. If the target population is clearly described then readers will be able to understand the relevance of the intervention to their own research or practice. Health inequalities, gender and ethnicity are features of the target population that may be relevant to intervention development processes.	2,3
4. Report how any published intervention development approach contributed to the development process	Many formal intervention development approaches exist and are used to guide the intervention development process (e.g. 6Squid (16) or The Person Based Approach to Intervention Development (17)). Where a formal intervention development approach is used, it is helpful to describe the process that was followed, including any deviations. More general approaches to intervention development also exist and have been categorised as follows (3):- Target Population-centred intervention development; evidence and theory-based intervention development; partnership intervention development; implementation-based intervention development; efficacy based intervention development; step or phased-based intervention development; and intervention-specific intervention development (3). These approaches do not always have specific guidance that describe their use. Nevertheless, it is helpful to give a rich description of how any published approach was operationalised	6
5. Report how evidence from different sources informed the intervention development process.	Intervention development is often based on published evidence and/or primary data that has been collected to inform the intervention development process. It is useful to describe and reference all forms of	4,5 Table 1

	evidence and data that have informed the development of the intervention because evidence bases can change rapidly, and to explain the manner in which the evidence and/or data was used. Understanding what evidence was and was not available at the time of intervention development can help readers to assess transferability to their current situation.	
6. Report how/if published theory informed the intervention development process.	Reporting whether and how theory informed the intervention development process aids the reader's understanding of the theoretical rationale that underpins the intervention. Though not mentioned in the e-Delphi or consensus meeting, it became increasingly apparent through the development of our guidance that this theory item could relate to either existing published theory or programme theory	12
7. Report any use of components from an existing intervention in the current intervention development process.	Some interventions are developed with components that have been adopted from existing interventions. Clearly identifying components that have been adopted or adapted and acknowledging their original source helps the reader to understand and distinguish between the novel and adopted components of the new intervention.	7
8. Report any guiding principles, people or factors that were prioritised when making decisions during the intervention development process.	Reporting any guiding principles that governed the development of the application helps the reader to understand the authors' reasoning behind the decisions that were made. These could include the examples of particular populations who views are being considered when designing the intervention, the modality that is viewed as being most appropriate, design features considered important for the target population, or the potential for the intervention to be scaled up.	10–13
9. Report how stakeholders contributed to the intervention development process.	Potential stakeholders can include patient and community representatives, local and national policy makers, health care providers and those paying for or commissioning health care. Each of these groups may influence the intervention development process in different ways. Specifying how differing groups of stakeholders contributed to the intervention development process helps the reader to understand how stakeholders were involved and the degree of influence they had on the overall process. Further detail on how to integrate stakeholder contributions within intervention reporting are available.	10–13
10. Report how the intervention changed in content and format from the start of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	n/a – this is the first iteration of the intervention

(*Continued*)

Continued.

Item description	Explanation	Page in manuscript
11. Report any changes to interventions required or likely to be required for subgroups	Specifying any changes that the intervention development team perceive are required for the intervention to be delivered or tailored to specific sub groups enables readers to understand the applicability of the intervention to their target population or context. These changes could include changes to personnel delivering the intervention, to the content of the intervention, or to the mode of delivery of the intervention.	n/a – we do not have enough data at the moment to make these sort of recommendations.
12. Report important uncertainties at the end of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	29
13. Follow TIDieR guidance when describing the developed intervention.	Interventions have been poorly reported for a number of years. In response to this, internationally recognised guidance has been published to support the high quality reporting of health care? Interventions and public health interventions. This guidance should therefore be followed when describing a developed intervention.	Appendix 2
14. Report the intervention development process in an open access format.	Unless reports of intervention development are available people considering using an intervention cannot understand the process that was undertaken and make a judgement about its appropriateness to their context. It also limits cumulative learning about intervention development methodology and observed consequences at later evaluation, translation and implementation stages. Reporting intervention development in an open access (Gold or Green) publishing format increases the accessibility and visibility of intervention development research and makes it more likely to be read and used. Potential platforms for open access publication of intervention development include open access journal publications, freely accessible funder reports or a study web-page that details the intervention development process	We intend to publish this paper in an OA journal. Study materials can be found at https://osf.io/xusby/

Appendix 2: TIDIeR checklist

Item number	Item	
	BRIEF NAME	
1.	Provide the name or a phrase that describes the intervention.	MIAMI
	WHY	
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	The MIAMI intervention aims to support General Practitioners and people with hypertension to maximise medication use to control blood pressure
	WHAT	
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	MIAMI training videos (GP intervention component) MIAMI booklet (GP intervention component) – https://osf.io/xusby/ Pre-consultation plan (Patient intervention component) – https://osf.io/xusby/ Blood pressure webpage on Croí website (Patient intervention component) – https://croi.ie/heart/high-blood-pressure/
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	The MIAMI intervention will be delivered at a minimum of one GP appointment during a three-month period The MIAMI intervention is a structured set of supports for GPs and patients with hypertension to facilitate adequate information exchange within consultations about long-term antihypertensive medication use and adherence skill development. Full details are in Table 6. It will include the following, where indicated: Patients • Wearing an ABPM and providing a urine sample for a chemical urine test of adherence. • Filling out a brief 'pre-consultation plan' before a GP consultation. • GPs • Training in how to structure a consultation around adherence issues. This will be provided through online videos and will take a maximum of 30 min. • A booklet with key takeaways from training videos and current guidance around blood pressure medication prescribing (from the European Society of Hypertension (3) and American College of Cardiology (18)) • A drop down menu on GP software which will provide a reminder of consultation guide and a list of resources that can be recommended to the patient (e.g. medication reminders – dontforget.ie and BP information – croi.ie/health/heart-conditions/high-blood-pressure/)

(*Continued*)

Continued.

Item number	Item	
	WHO PROVIDED	
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	GPs – 30 min online training in how to structure a consultation around medication taking and adherence issues
	HOW	
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	GPs – Training provided online. GPs can access individually and undergo training at own time and pace. Patients – Face to face consultation with GP
	WHERE	
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	GPs – online Patients – at GPs clinic
	WHEN and HOW MUCH	
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	The MIAMI intervention will be delivered at a minimum of one GP appointment during a three-month period. Consultations typically last 15–20 min.
	TAILORING	
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	GP component is not personalised. Patient component can be personalised by the GP – they will use their judgement and training to decide what adherence support a patient may need. Patients may decide themselves whether to being the pre-consultation plan to their GP appointment.
	MODIFICATIONS	
10.	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	NA (intervention not yet delivered)
	HOW WELL	
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	We are planning to assess fidelity during the pilot RCT through a checklist on the GP software.
12.	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	NA (intervention not yet delivered)