OPEN ACCESS

# Implementation of a patient-centred complex intervention to improve Initial Medication Adherence to cardiovascular disease and diabetes treatments in primary care (the IMA-cRCT study): a mixed-methods process evaluation

Carmen Corral-Partearroyo ,[1,2,3] Alba Sánchez-Viñas ,[1,3,4] María Teresa Peñarrubia-María,[1,3,5] Montserrat Gil-Girbau ,[1,6] Ignacio Aznar-Lou,[1,3] Claudia Palma-Vasquez ,[1,6] Carmen Gallardo-González ,[1,5,6] María del Carmen Olmos-Palenzuela ,[1,5,6] Maria Rubio-Valera [1,3,4]

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/bmjqs-2024-018403).

For numbered affiliations see end of article.

**Correspondence to**
Dr Maria Rubio-Valera;
maria.rubio@sjd.es

Received 18 December 2024
Accepted 22 May 2025

Check for updates



**To cite:** Corral-Partearroyo C, Sánchez-Viñas A, Peñarrubia-María MT, *et al*. *BMJ Qual Saf* Epub ahead of print: [please include Day Month Year]. doi:10.1136/bmjqs-2024-018403

## ABSTRACT

**Introduction** The initial medication adherence (IMA) intervention aims to improve adherence to cardiovascular disease (CVD) and diabetes treatments in primary care (PC) through standardised shared decision-making (SDM) and healthcare professional (HCP) collaboration (general practitioners (GPs), nurses and pharmacists). This study assessed the intervention's implementation (strategies, fidelity and integration into routine practice—based on the Normalisation Process Theory), mechanisms of action and the role of context.

**Methods** The IMA-cRCT was an effectiveness-implementation cluster-Randomised Controlled Trial involving 24 Spanish PC centres (>300 HCP; >3000 patients) based on real-world evidence. This nested process evaluation used quantitative (monitoring data; HCP questionnaires) and qualitative methods (field diaries; 36 semistructured individual interviews and two focus groups (19 patients, 28 HCPs)). Quantitative data explored implementation and context and were analysed descriptively, while qualitative data examined implementation, mechanisms of action and context and were analysed using framework analysis. Both analyses were integrated for interpretation.

**Results** Intervention implementation fidelity (6.5/10) and normalisation into clinical practice (7.6/10) were adequate, particularly regarding SDM and use of decision aids. HCPs recognised the importance of SDM, although some assumed it was already part of routine practice. The anticipated mechanisms of action were moderately supported. HCPs' knowledge and attitudes towards SDM improved as they acknowledged its relevance to practice. Some patients reported participation in decision-making, while others preferred the GP to decide on their behalf. Patients found leaflets helpful for understanding information. Contextual factors influencing the intervention were mainly organisational, such as lack of time and familiarity with SDM.

**Conclusions** The interprofessional SDM-based IMA intervention was considered beneficial for patients and HCPs, with adequate implementation fidelity and normalisation into practice. The intervention was important for HCPs, and patients accepted it. However, greater effort is needed to extend SDM throughout healthcare, moving towards patient-centred care. These results have enhanced understanding of SDM interventions and support their refinement for future implementation.

**Trial registration number** ClinicalTrials.gov, NCT05026775.

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Challenges with medication initiation and long-term adherence to chronic treatments can impact disease management and patients' clinical outcomes.

⇒ Patient-centred care interventions are increasingly in the spotlight and show promising results in increasing patient health literacy, satisfaction and autonomy in decision-making for chronic treatments. Yet, evidence on how these interventions are implemented and work remains limited.

### WHAT THIS STUDY ADDS

⇒ This study evaluates the implementation of a shared decision-making (SDM) intervention alongside a cluster-randomised controlled trial (cRCT). These findings promote an in-depth understanding of how the initial medication adherence (IMA) intervention was implemented and worked, and they support the development of evidence-based interventions in healthcare.

⇒ This paper outlines an approach to the design and development of process evaluations of complex interventions and offers a guide to other researchers developing process evaluations for cRCTs based on real-world evidence in primary care.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Patient-centred care and SDM are viewed positively by both professionals and patients; however, changes to traditional practices and healthcare system structures are needed to facilitate their wider adoption as a care model.

## INTRODUCTION

Initial medication adherence (IMA) refers to the starting point 'when the patient takes the first dose of a prescribed medication'.[1] The prevalence of non-initiation varies by medication and context (2–40%)[2–4] and is influenced by prescriber and patient characteristics, their context and disease and treatment perceptions.[2 4–6] Effective patient-centred interventions are needed to support adherence, as it can impact disease management,[7–10] while increasing costs of care.[11] To date, most interventions addressing initiation have been based on patient reminders, none were theory based and all showed a high risk of bias in their evaluation.[12–16]

The IMA intervention was developed to improve initiation and secondary adherence to cardiovascular disease (CVD) and diabetes treatments in primary care (PC).[6 17–22] It is a complex, multidisciplinary, patient-centred intervention that promotes shared decision-making (SDM) when a new prescription is issued. SDM is a healthcare quality standard and shows promise in increasing patient self-efficacy regarding health decisions.[23 24] However, evidence on the effect of SDM on patient health literacy, satisfaction with care and medication adherence is inconclusive.[25–27]

Randomised controlled trials (RCTs) focus on effectiveness evaluations and generally do not describe the intervention implementation process, its mechanisms of action and for whom and in which contexts it works.[28] Process evaluations are essential in determining how intervention components interact to impact outcomes and guiding optimisation of the intervention for future implementation, scalability and generalisation to other contexts.[28] This study presents a process evaluation embedded in the IMA-cluster-RCT (cRCT) which aimed to: (1) assess the implementation of the IMA intervention, implementation strategies, fidelity to intervention protocol and understand how it becomes integrated into PC practice, (2) explain the intervention mechanism of action and (3) identify contextual factors that can influence its implementation and active mechanisms. The results of this process evaluation served to explain the cRCT results and refine the IMA intervention for future implementation. These results are presented and discussed in the effectiveness evaluation paper.[29]

## METHODS

### Study design

The IMA-cRCT was a type I hybrid effectiveness-implementation trial conducted in 24 PC centres and 37 community pharmacies within the catchment area of the 12 intervention group (IG) centres between March and September 2022, with a 1-year patient follow-up.[21 22 29 30]

The embedded mixed-methods process evaluation was designed following Medical Research Council guidelines for the development and evaluation of complex interventions.[28 31] Therefore, it explored three interactive domains that could influence trial outcomes: (1) *implementation* of the intervention was explored by assessing *implementation strategies* or methods used to adopt the intervention, *fidelity* or the degree to which the intervention was implemented as intended in the original protocol and *normalisation* or processes through which the intervention was integrated into routine practice using quantitative and qualitative methods. Normalisation was assessed using Normalisation Process Theory (NPT) and evaluated four constructs: *coherence* (how professionals define and understand it), *cognitive participation* (how professionals engage and commit to sustaining it), *collective action* (how professionals put it into practice) and *reflexive monitoring* (how professionals assess and monitor it)[32]; (2) the intervention *mechanisms of action* that bring about any effects and explain the intervention logic using qualitative methods; and (3) the *context* that could influence implementation and its active mechanisms using quantitative and qualitative methods.

This study is reported according to the Standards of Reporting Implementation Studies (StaRI) checklist[33] and the Good Reporting of A Mixed Methods Study (GRAMMS) checklist for mixed-methods research.[34]

### Intervention

The IMA intervention is a complex multidisciplinary intervention that aims to improve medication adherence and clinical outcomes and reduce cardiovascular risk, based on the non-initiation model[6 19] and the principles of SDM.[23 24] It promotes health literacy and

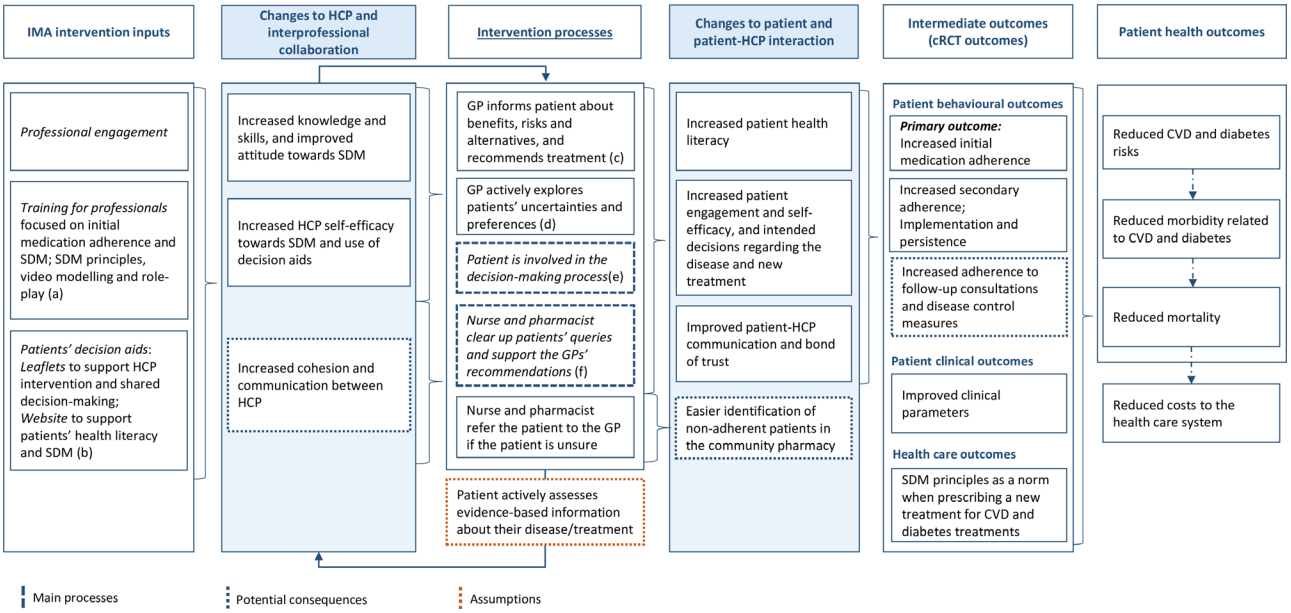


**Figure 1** IMA intervention logic model. Intervention Behaviour Change Techniques (BCTs)[35]: (a) 4.1 Instruction of how to perform a behaviour, 6.1. Demonstration of the behaviour and 8.1. Behavioural practice/rehearsal. (b) 12.5. Adding objects to the environment. (c) 5.1. Information about health consequences and 9.1. Credible source. (d) 1.2. Problem-solving (e) 1.9. Commitment. (f) 3.1. Social support (unspecified). CVD, cardiovascular disease; GP, general practitioner; HCP, healthcare professional; IMA, initial medication adherence; SDM, shared decision-making.

SDM when the general practitioner (GP) prescribes a new lipid-lowering, antihypertensive, antiplatelet and/or glucose-lowering treatment. Nurses and pharmacists support the information provided by the GP, thus standardising the message and promoting collaboration between the professionals involved in the process. Patients could have a pre-existing therapeutic relationship with the professionals.

The intervention logic model (figure 1) illustrates the intervention implementation strategies (inputs) and intervention processes linked to Behaviour Change Techniques (BCTs)[35] and the hypothesised mechanisms of action (changes to healthcare professionals (HCPs) and interprofessional collaboration and changes to patient and patient-HCP interactions) to influence adherence (intermediate outcome) and ultimately patient health outcomes. Details on intervention development are described elsewhere.[21] The implementation strategies consisted of *professional engagement* to promote the intervention and improve attitudes towards it by holding information sessions with managers and professionals; *training for professionals* focused on IMA and SDM to increase knowledge and professionals' self-efficacy, including role-playing; and *intervention decision aids* (leaflets and website[36] translated into the most spoken languages) to support the intervention implementation and standardise practice. GPs, nurses and pharmacists were trained together to increase cohesion.

### Usual care

HCPs in the control group were asked to provide usual care. In this, GPs generally decide how to provide information, nurses monitor chronic treatments, and community pharmacists explore patients' queries about the medication.

### Setting and participants

The IMA-cRCT was carried out in public PC centres and private community pharmacies in Catalonia, Spain. The Spanish National Health system provides universal coverage and is primarily tax-funded, with free access to care except for pharmaceutical prescriptions, which require co-payment.[37] PC is the gateway to the public healthcare system and where most long-term CVD and diabetes treatments are prescribed. PC funding is mainly dependent on regional budgets, with generally fewer resources allocated to PC compared with hospital care. PC centres are organised into teams comprised of physicians, community nurses, other HCPs and administrative staff. Community pharmacies are private healthcare establishments of public interest.[37] Their public funding derives exclusively from the dispensing of medicines and medical products. Patients are assigned to one GP and one nurse. GPs prescribe treatments using an electronic prescription system, which can only be dispensed at free-of-choice community pharmacies.[22 37] The physical distance between PC centres and community pharmacies, along with poor communication among professionals and a lack of established collaborative practices, has traditionally limited direct interaction and interprofessional collaboration.[38]

The IMA-cRCT included over 300 professionals and 3000 patients overall. Professionals from the IG (83 GPs, 69 nurses and 58 pharmacists) completed

the training and implemented the intervention over 7 months. Each PC centre had a coordinator, either a GP or nurse participating in the study, who was contacted regularly during the study period. The process evaluation sampling strategy was conditioned by the trial cluster design.

### Professionals

All IG professionals were asked to complete questionnaires, and professionals from eight centres were invited to participate in qualitative interviews. Maximum sample variability was ensured for both PC centres (location, rurality, area socioeconomic status, population size and nationality, and professionals' workload perceptions and motivation at pre-implementation) and professionals (professional category, age, sex and years of experience).

### Patients

Patients in the IG were identified by PC coordinators, who may or may not have been the patient's treating GP or nurse, and invited to participate in an interview. PC coordinators contacted patients who had been prescribed a new medication during the study period, 15 days to 1 month after the consultation, inviting them to participate while avoiding mention of adherence or the IMA intervention. After acceptance, the research team contacted them to provide further information and schedule interviews. Recruitment followed maximum variation criteria based on age, sex, nationality, medication prescribed, education and employment status.

## Data collection and analysis

### Quantitative methods

1. *Monitoring data* were collected from trial operative sheets (professional engagement, training attendance rate and intervention tools usage) and PC centre demographic records (area socioeconomic status, population size and nationality, and training centre) to assess implementation strategies, fidelity and understand the context.
2. *Pre-implementation professionals' questionnaires* were completed to assess training quality and professionals' workload and motivation perceptions. 3-month and 7-month *post-implementation questionnaires* were emailed to professionals to assess implementation fidelity and normalisation into routine practice. Five items assessed fidelity based on the intervention protocol recommendations: apply SDM principles when prescribing a new medication (GP) or encountering a patient with a new prescription (nurses and pharmacists); use of decision aids (leaflets and a website); and, in case of a first telephone consultation, follow-up with a second telephone consultation to address any queries or concerns regarding the prescription. 22 items assessed normalisation divided into NPT constructs based on the Normalisation Measure Development (NoMAD) questionnaire[39] and adapted for this specific use. All items were rated from 1 (strongly disagree) to 10 (strongly agree). Evidence on questionnaire instrument validity was collected based on content, response process and internal structure that supports its use (online supplemental file 1).

Descriptive analyses and linear regression models were used to assess differences between professionals (category, sex and experience) and PC centres and pharmacies (location, population size and nationality) using Stata V.17.

### Qualitative methods

1. *Field diaries* were completed by both the research team and the IG PC centre coordinators with data on implementation barriers and facilitators and the organisation of PC centres and pharmacies as reported by participating professionals.
2. *Individual semistructured interviews* with professionals and patients were conducted throughout the trial's 7-month fieldwork to explore implementation strategies, fidelity and normalisation into routine practice; participants' perceptions and experiences to assess the mechanisms of action, perceived impact on patients' and professionals' behaviours; and contextual factors. The interviews were conducted by telephone with professionals and face to face or by telephone (n=4) with patients. Interviews lasted 30–70 min and patients were reimbursed for their time. Two *focus groups* with professionals explored conflicting themes that arose during

**Table 1** Sociodemographic information on quantitative and qualitative professional samples

| | Quantitative professional sample | | | Qualitative professional sample | | |
|---|---|---|---|---|---|---|
| | GPs (n=59) | Nurses (n=41) | Pharmacists (n=39) | GPs (n=11) | Nurses (n=7) | Pharmacists (n=10) |
| Mean age (SD) | 47.64 (8.32) | 45.11 (9.27) | 46.67 (9.54) | 50.32 (8.97) | 46.90 (5.66) | 47.77 (9.01) |
| Sex: female, n (%) | 45 (76.27) | 39 (95.12) | 28 (71.79) | 7 (63.64) | 6 (85.71) | 8 (80.00) |
| Nationality: Spanish, n (%) | 53 (89.83) | 40 (97.56) | 31 (79.49) | 11 (100) | 6 (85.71) | 9 (90.00) |
| Mean years of experience (SD) | 18.45 (8.32) | 13.73 (8.97) | 19.06 (10.69) | 22.45 (7.84) | 20.17 (4.45) | 18.30 (9.84) |
| Student supervisor, n (%) | 33 (55.93) | 22 (53.66) | n/a | 7 (63.64) | 4 (57.14) | n/a |
| Type of PCC/pharmacy: urban, n (%) | 44 (74.58) | 33 (80.49) | 31 (79.49) | 9 (81.82) | 3 (42.86) | 7 (70.00) |

Sex: female, male; Nationality: Spanish, other; Student supervisor: yes, no; Type of PCC/pharmacy: urban, rural.
GPs, general practitioners; PCC, primary care centre; SD, standard deviation.

individual interviews and shared opinions regarding the IMA intervention. Predefined themes were explored deductively, such as the main intervention processes and normalisation into routine practice, and open questions were used to explore participants' experiences and perceptions inductively (online supplemental file 2 tables 1–3). Focus groups (three and eight professionals) were conducted by videoconference and lasted 45 min each. After each interview, researchers circulated a summary for participants' review. Interviews were audio recorded, anonymised and transcribed.

Qualitative data were analysed following framework analysis.[40] Field notes and transcripts were included and organised by group (PC centres) and cases (professionals and patients). NVivo software was used for data management. Three researchers familiarised themselves with the data and analysed the transcripts separately by interpreting the results and mapping them onto intervention processes, NPT constructs and the ecological model to understand the contextual factors (deductively),[32 41] while remaining open to new themes that emerged from the data on participants' experiences and perceptions (inductively) to generate coding frameworks. The researchers triangulated coding frameworks until a final version was generated and applied to all data. Data were compared by group and between cases while charting into the framework matrix for interpretation.

### Triangulation of results

Quantitative and qualitative results were combined into a framework matrix and interpreted together.[42] A final summary of findings was produced and presented to all coauthors for review, clarification and final interpretation.

### Deviations from study protocol

There were protocol[21] deviations in line with the dynamic nature of the study. Intervention protocol fidelity was to be explored through questionnaires and field diaries, but interviews were conducted to provide richer information. See online supplemental file 2 table 4 and online supplemental file 2 figure 1 for data sources and collection techniques per domain evaluated and study timeline deviations.

## RESULTS

Tables 1 and 2 present participant sociodemographic characteristics. Online supplemental file 3 tables 1–3 show further characteristics of participants and PC centres. The quantitative methods involved 139 professionals (66% response rate). The qualitative methods included 28 professionals (34 declined to participate due to time restrictions). 38 patients were contacted, of whom 19 declined to participate due to time restrictions and personal reasons, leaving 19 patients who participated.

**Table 2** Sociodemographic information on the qualitative patient sample

| Qualitative patient sample | Patients (n=19) |
|---|---|
| Mean age (SD) | 53.38 (12.19) |
| Sex: female, n (%) | 8 (42.11) |
| Nationality: Spanish, n (%) | 15 (78.95) |
| Type of PCC/pharmacy: urban, n (%) | 12 (63.16) |
| Medication prescribed, n (%)* | |
| Antihypertensive | 10 (52.36) |
| Lipid-lowering | 4 (21.05) |
| Antiplatelet | 2 (10.53) |
| Oral glucose-lowering | 8 (42.11) |
| Injectable glucose-lowering | 3 (15.79) |
| >1 CVD or diabetes diagnosis, n (%) | 11 (57.89) |
| Educational status, n (%) | |
| No formal education | 1 (5.26) |
| Primary education | 4 (21.05) |
| Secondary education | 9 (47.37) |
| University education | 4 (21.05) |
| Not reported | 1 (5.26) |
| Employment status, n (%) | |
| Unemployed | 1 (5.26) |
| Employed | 13 (68.42) |
| Retired/pensioner | 4 (21.05) |
| Not reported | 1 (5.26) |
| Income (€, monthly), n (%) | |
| <500 | 2 (10.53) |
| 500 to <1000 | 5 (26.32) |
| 1000 to <2000 | 5 (26.32) |
| 2000 to <3000 | 2 (10.53) |
| 3000 to <4000 | 3 (15.79) |
| 4000 to <6000 | 1 (5.26) |
| Not reported | 1 (5.26) |

Sex: female, male; Nationality: Spanish, other; Type of PCC/pharmacy: urban, rural; >1 CVD or diabetes diagnosis: yes, no.
*Each patient may have had more than one new medication prescribed.
CVD, cardiovascular disease; PCC, primary care centre; SD, standard deviation.

Quantitative and qualitative results are reported together for each domain to offer deeper insights and highlight their complementarity. Professionals' fidelity and normalisation questionnaire results correspond to the 7-month post-implementation responses. Online supplemental file 3 table 4 compares 3-month and 7-month post-implementation results.

### Implementation

#### Implementation strategies

See online supplemental file 3 table 5 for *professional engagement* details. Professional recruitment rate was higher among GPs (63.3%) than nurses (45.1%) and community pharmacies (37.6%). Training attendance was high across all professional categories (89% to 96.8%).

Professionals rated all aspects of the quality of the *training for professionals* highly, including organisation, materials, objectives, methodology and applicability to clinical practice. Two highly valued aspects were combined training of GPs, nurses and pharmacists to encourage collaboration and role-play; *"You have heard about SDM, you have read… But you need a little practice, if you do not practice it in a course before, even briefly, if you start directly without practicing, you think: "How the hell do I do it?" (Nurse-1)"*. Negative aspects included training duration, scheduling difficulties and lack of training continuity.

*Leaflets* were described by GPs and nurses as facilitators to implementation, who highlighted their value in supporting SDM at the consultation; *"Because you create the best possible environment for the SDM to take place. (GP-2)"*, adding; *"We assume that the moment you explain it, they have understood it all and will remember it and in most cases it's not like that. It's about being able to take it with you and review it later, and to have the chance to take notes. (GP-7)"*. They valued their format, content, plain language and the language translations. Patients highlighted their value in understanding the information; *"It was like a summary, a little summary of what he had explained to me. Let's say like language that was easier to understand, not so medical. (Patient-5)"*, although few reported subsequently consulting it.

### Fidelity

Professionals scored higher on fidelity when implementing SDM principles than when using decision aids for support. Nonetheless, leaflets were used more frequently than the website (table 3). Some professionals reported not using the leaflets at all times, either because they forgot about them or did not have them to hand, although they provided the same information; *"I maybe didn't always give them the leaflet but I explained its contents to them. (Nurse-4)"*. Others reported selecting information based on their professional opinion or not applying SDM when urgent treatment was required; *"I may have adapted some things based on the drugs they are taking. Or I may not be completely neutral when explaining the options available, as I also have preferences. (GP-1)"*.

Overall, nurses scored highest on fidelity (mean=7.4; $p<0.05$ compared with GPs and pharmacists). GPs acknowledged adapting the intervention according to the patient's needs, and pharmacists frequently reported overlooking it and generally providing information to patients facing adherence challenges or with queries about the treatment; *"I usually did it [the intervention] if they already had questions. (Pharmacist-2)"*.

Fidelity was also assessed through patient experiences. Patients reported that the first consultation was with the GP (as per intervention protocol) or nurse, depending on the PC centre, and highlighted the role of nursing regarding new medications for chronic pathologies; *"The doctor is the one who makes the diagnosis but the nurse is the one who monitors you. So, I practically trust the nurse more in chronic treatments… (Patient-3)"*. Most patients mentioned the professional giving health information at the time of prescription, yet leaflets were not always used. Two patients mentioned the website being recommended, but none consulted it. Half of the patients recalled SDM, based mainly on how the professional presented the medication as a choice or as the only option; *"She gave me the information, she told me that the pill helped to improve blood pressure, and so I decided that it was perfect. (Patient-17)"*. Overall, they reported a lack of information support at community pharmacies; *"No, she [the pharmacist] didn't ask me anything, she just looked at the prescriptions and gave it to me. (Patient-18)"*.

### Normalisation

Normalisation of the IMA intervention into clinical practice was assessed through questionnaires (table 3 and figure 2) and qualitative responses (see online supplemental file 3 table 6 for details on main themes identified).

1. *Coherence*. Professionals defined SDM as the core of the intervention independently of decision aids; *"I suppose the aim is to do all the explaining, make them understand and let them decide what options they have and what they want to do… But whether to give it to them in writing or not, that depends on the patient. (GP-5)"*. However, differentiation from usual care had the lowest coherence score (mean=6.3) and was particularly low in the case of pharmacists (mean=5.9). This was consistent with the qualitative results, where some considered the intervention was already in line with their existing practice; *"We haven't done much more than what we normally do. (Pharmacist-2)"*. Depending on the PC centre, professionals understood their roles and tasks differently. In some PC centres, nurses mainly monitored chronic conditions and thus implemented SDM at the time of prescription. Pharmacists understood their role but considered it secondary to other professionals; *"Our work doesn't make much sense unless previous work has been done. As for SDM, that's what this is all about. (Pharmacist-1)"*.
2. *Cognitive participation*. Professionals scored low on encouraging other professionals to implement the IMA intervention (mean=4.4). Nonetheless, they believed the IMA intervention to be a legitimate part of their role (mean=8.0). GPs and nurses were willing to continue implementing it once the trial ended as they saw the benefits for patients; *"It really structures a way of modifying or introducing a new drug in agreement with the patient, with the tools that, in some way, can improve therapeutic adherence. (GP-4)"*. Pharmacists were less motivated due to a perceived lack of interest from patients. Broadly, professionals suggested ideas to sustain it, such as electronic system alerts when issuing new prescriptions and

**Table 3** Fidelity and normalisation questionnaire scores for professionals 7 months post implementation

| | Overall (n=139) Mean (SD) | GPs (n=59) Mean (SD) | Nurses (n=41) Mean (SD) | Pharmacists (n=39) Mean (SD) |
|---|---|---|---|---|
| **Fidelity** | 6.53 (1.97) | **6.17 (1.94)** | 7.37 (1.46) | **6.21 (2.26)** |
| I implement the IMA intervention based on the principles of SDM | 7.71 (1.79) | 7.61 (1.80) | 8.14 (1.24) | **7.41 (2.20)** |
| I use leaflets to support SDM | 6.99 (2.37) | **6.63 (2.36)** | 8.07 (1.79) | **6.41 (2.60)** |
| I give the leaflet to the patients so that they can evaluate it outside the consultation | 6.89 (2.53) | **6.49 (2.45)** | 8.00 (1.84) | **6.33 (2.94)** |
| I recommend patients to consult the website (www.iniciadores.es) | 5.52 (2.50) | **5.27 (2.47)** | 6.68 (2.03) | **4.67 (2.61)** |
| In the case of prescriptions made through telephone consultation, I call the patient a week later to resolve queries about the prescription | 5.29 (2.69)* | **4.85 (2.89)** | 5.93 (2.26) | n/a |
| **Normalisation** | | | | |
| General experience | | | | |
| I am familiar with the IMA intervention based on SDM | 8.02 (1.70) | 8.07 (1.71) | 8.32 (1.08) | 7.64 (2.13) |
| I think the intervention has become a normal part of my clinical practice | 7.43 (1.95) | 7.34 (1.99) | 7.93 (1.13) | **7.05 (2.44)** |
| Coherence | 7.08 (1.58) | **6.94 (1.46)** | 7.70 (1.10) | **6.63 (1.98)** |
| There are differences between the IMA intervention based on SDM and my previous clinical practice (Differentiation) | 6.34 (2.06) | 6.20 (2.07) | 6.98 (1.62) | **5.87 (2.31)** |
| I consider that PCC/pharmacy professionals have a shared understanding of the purpose of the IMA intervention (Communal specification) | 7.33 (1.95) | 7.27 (1.82) | 7.49 (1.63) | 7.26 (2.44) |
| I understand how the IMA intervention impacts my clinical practice (Individual specification) | 6.97 (1.97) | **6.76 (1.84)** | 7.90 (1.50) | **6.31 (2.27)** |
| I can see the added value of the IMA intervention for my clinical practice (Internalisation) | 7.66 (1.92) | **7.53 (1.77)** | 8.41 (1.26) | **7.08 (2.42)** |
| Cognitive participation | 7.15 (1.60) | 6.97 (1.59) | 7.58 (1.13) | 6.99 (1.94) |
| I have encouraged other professionals to implement the IMA intervention (Initiation) | 4.44 (2.77) | 4.39 (2.79) | 4.83 (2.71) | 4.10 (2.83) |
| I believe that participating in the IMA intervention is part of my professional role (Legitimation) | 8.02 (1.79) | **7.73 (1.76)** | 8.46 (1.31) | 8.00 (2.18) |
| I am open to working with my colleagues in new ways to implement the IMA intervention (Enrolment) | 7.94 (1.80) | 7.71 (1.86) | 8.41 (1.26) | 7.79 (2.10) |
| I will continue to support the IMA intervention and implement the principles of SDM (Activation) | 8.22 (1.61) | 8.05 (1.61) | 8.61 (1.02) | 8.05 (2.01) |
| Collective action | 8.10 (1.43) | 8.02 (1.57) | 8.41 (0.92) | 7.90 (1.63) |
| I consider the IMA intervention can be easily integrated into my clinical practice (Interactional workability) | 7.73 (1.89) | 7.66 (1.85) | 8.27 (1.32) | **7.26 (2.30)** |
| The IMA intervention improves the relationship between professionals (GPs, nurses and pharmacists) (Relational integration) | 7.75 (2.05) | 7.78 (2.03) | 7.98 (1.62) | 7.46 (2.46) |
| I have confidence in other professionals' ability to implement the IMA intervention (Relational integration) | 8.05 (1.71) | 7.88 (1.84) | 8.29 (1.27) | 8.05 (1.90) |
| The role of each professional in the IMA intervention is appropriate to each professional category (medicine, nursing and pharmacy) (Skill set Workability) | 8.19 (1.63) | 8.03 (1.64) | 8.46 (1.23) | 8.13 (1.95) |
| Sufficient training is provided to enable professionals to implement the IMA intervention (Skill set Workability) | 8.08 (1.85) | 7.95 (2.07) | 8.44 (1.32) | 7.90 (1.94) |
| The resources of the IMA intervention are sufficient to support SDM (Contextual integration) | 8.24 (1.63) | 8.19 (1.75) | 8.71 (1.03) | **7.82 (1.85)** |
| The PCC/pharmacy management team adequately supports the IMA intervention (Contextual integration) | 8.70 (1.68) | 8.66 (1.83) | 8.73 (1.32) | 8.72 (1.83) |
| Reflexive monitoring | 7.95 (1.49) | 7.87 (1.34) | 8.26 (1.12) | 7.74 (1.94) |
| I am aware of evidence that supports the effects of SDM on which the IMA intervention is based (Systematisation) | 7.39 (1.90) | 7.51 (1.48) | 7.20 (2.02) | 7.41 (2.33) |
| PCC/pharmacy professionals agree that implementing the IMA intervention is worthwhile (Communal appraisal) | 8.09 (1.63) | 7.97 (1.53) | 8.34 (1.33) | 8.00 (2.01) |
| I value the effects that the IMA intervention has had on my clinical practice (Individual appraisal) | 8.04 (1.77) | **7.80 (1.81)** | 8.56 (1.10) | 7.85 (2.16) |
| Professional opinions about the intervention can be used to improve the IMA intervention in the future (Reconfiguration) | 8.18 (1.60) | 8.03 (1.53) | 8.56 (1.12) | 8.00 (2.05) |
| I can improve how I work with the IMA intervention (Reconfiguration) | 8.07 (1.77) | 8.07 (1.64) | 8.68 (1.15) | **7.44 (2.26)** |

Values marked in bold indicate significant differences between nurses (ref) and other professional categories.
*GPs and nurses (n=100).
GPs, general practitioners; IMA, initial medication adherence; SD, standard deviation; SDM, shared decision-making.

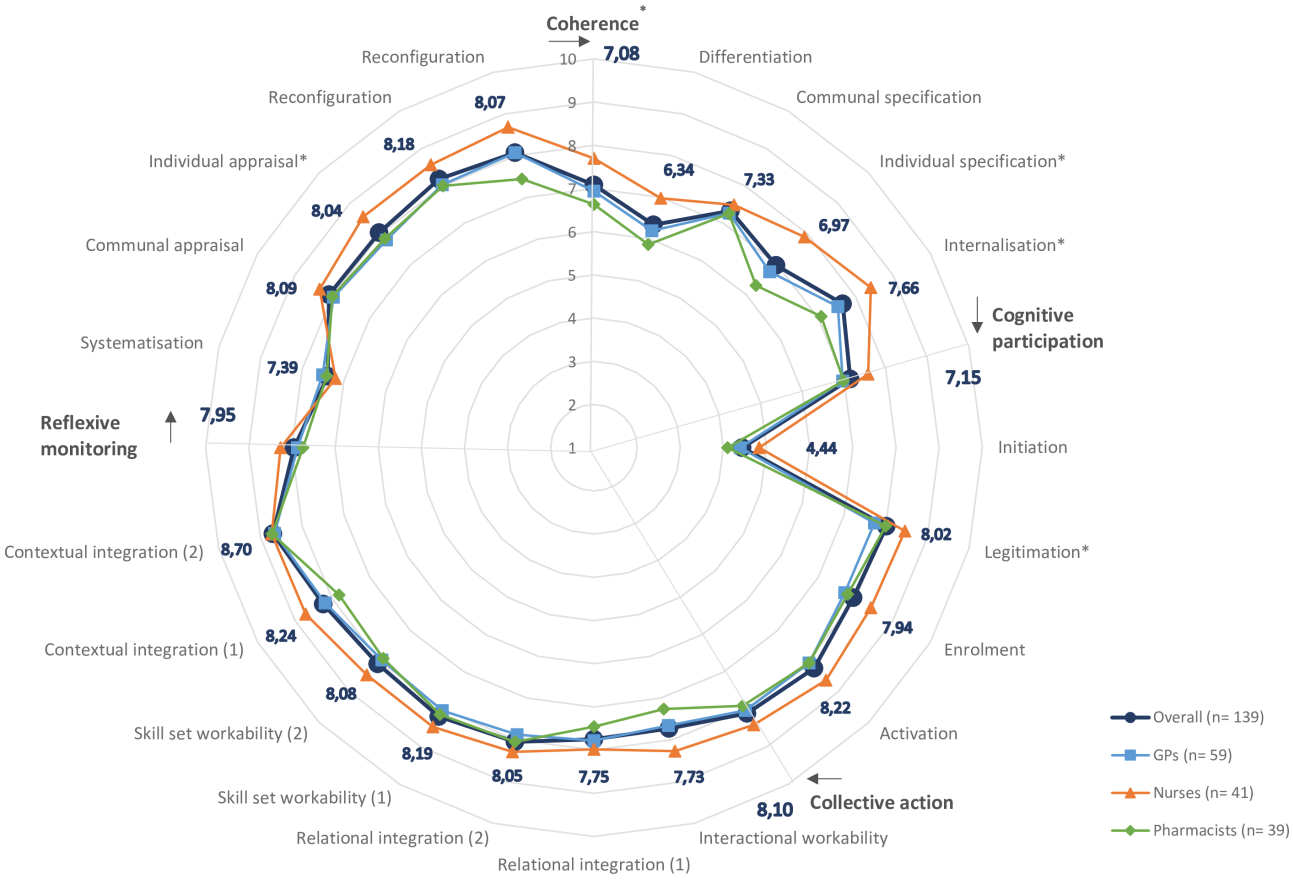


**Figure 2** Mean scores for Normalisation Process Theory constructs and subconstructs[39] across all professionals and professional categories. *Statistically significant differences among professionals. GP, general practitioner.

continued SDM training, although these rely on the wider system.

3. *Collective action* had the highest mean score (mean=8.1). PC centre professionals considered integration easier than pharmacists. Professionals trusted their skills and those of their colleagues and highlighted the role of each professional in the care of chronic patients; *"Medicine is more about making decisions together with the patient (…) But both nursing and pharmacy have a role in monitoring and follow-up (…) I think we are all in the same team. (GP-3)"*.
4. *Reflexive monitoring*. Professionals valued the intervention effect on their clinical practice (mean=7.9), with nurses having the highest score (mean=8.3). Even though professionals did not directly monitor intervention effects, they showed interest in its impact, trial results and influence on adherence. GPs and nurses reported improvements in SDM awareness and their role as educators and promotors of patient autonomy; *"Because you adopt the role of professional more… More of an educator, more of a motivator. Especially the aspect of educating the patient and giving them autonomy. (GP-1)"*. Pharmacists generally considered it difficult to detect non-initiation but acknowledged being more attentive to patients facing adherence issues. Generally, there was a sense of increased time invested, accompanied by a feeling that this could lead to timesaving in subsequent encounters; *"You spend more time over the consultation, but I believe that in the long run, when you invest more time in a patient one day, you save it on others. (GP-1)"*.

On the whole, nurses reported the highest fidelity and normalisation into routine practice. Statistically significant differences between nurses, GPs and pharmacists are observed in table 3. There were no significant differences between other professionals or PC centres and pharmacy characteristics.

### Mechanisms of action

Qualitative results detailed the intervention mechanisms that influence participants' behaviours (see online supplemental file 3 table 7 for details on main themes identified). *Changes to HCPs and interprofessional collaboration* were assessed through professionals' experiences. Professionals' attitudes towards SDM largely improved as they understood the importance of increasing patients' health literacy and decision-making autonomy; *"I think, in general, it should always be used. In this case, we have applied it to new treatments, but I think it always has to be there. Whatever you ask them [patients], ordering tests or anything to do with them, they have to be well informed and accept it, of course. (Nurse-2)"*. Nevertheless, some professionals thought SDM could not be implemented with all patients, depending on,

for instance, their bond of trust or differing patient profiles; *"My experience is that for some patients it does work, but it is not for everyone. It depends on each patient's profile. But, of course, you are deciding something about another person and I believe that the fact that the other person also decides if they want to do it, how they want to do it and so on, is very important. (GP-7)"*. Individuals from all professional categories agreed that cohesion and communication did not change because of the intervention. GPs and nurses generally had favourable relationships with each other and reported it as an implementation facilitator, whereas none reported interprofessional collaboration between PC centres and pharmacies.

*Changes to patient and patient–HCP interactions* were assessed through professionals' and patients' experiences. Professionals perceived that the IMA intervention helped patients understand their disease and treatment and therefore increased health literacy; *"It helps the patient a lot to position themselves, about what the disease is and what therapeutic options they have. Knowing where you are is always important. (GP-2)"*. As perceived by professionals, patients asked more questions and reflected more on their preferences, which could increase patients' confidence regarding the medication. Patients with previous personal or familial pathology experiences reported no new knowledge gained after the intervention. Those who reported knowledge gained emphasised learning new information about the pharmacological treatment, adverse effects and disease complications. Nevertheless, a few patients reported that detailed information could increase their concerns; *"I'm a bit of a hypochondriac and too much information is counterproductive for me. I tend to get stressed, to worry about everything, to be very emotional. (Patient-19)"*. Professionals believed patients appreciated being involved in the decision, which increased patient autonomy and adherence; *"Any person you let choose and decide on any aspect, you raise their self-esteem and improve compliance and improve involvement. (GP-1)"*, as well as humanisation of clinical care; *"Feeling that they are included and that you are treating them as people, not as numbers or diseases. (GP-11)"*. However, professionals perceived not all patients wanted to be involved in the decision, and some patients expressed discomfort; *"Look, I haven't studied medicine, I have to go to medical school, study for five years, so that we could talk face to face and they could explain everything to me, it is impossible! (Patient-10)"*. Patients who participated in the decision valued being involved, although some recognised that not being involved would not have altered the outcome; *"If I hadn't been part of it [the decision], if she hadn't asked me about it, it wouldn't have made any difference. But when she mentioned it to me, I said: "Well yes, if my opinion is useful, then sure. (Patient-18)"*. At last, even though professionals believed the IMA intervention could improve patient–professional trust and reduce power imbalances, no participant reported relationship changes.

### Context

Contextual factors that influenced implementation and intervention active mechanisms are presented in line with the ecological model and distinguish among microlevel (patient), mesolevel (organisation and culture) and macrolevel (wider environment)[41 43] (see online supplemental file 3 table 8 for details on main themes identified).

As microlevel factors, professionals defined patient profiles as facilitators or barriers to implementing SDM. They emphasised low education, financial difficulties and cultural and language differences as barriers to providing health education and involving patients in decisions. Additionally, they considered age to be an important aspect. They perceived that the younger the patient, the more willing they were to be involved in the decision; *"They are usually middle-aged people, not very old, who like to participate, because they are worried. They want to participate. (GP-6)"*.

As mesolevel factors, PC centre professionals highlighted longitudinality as a facilitator to SDM, enabling patients to visit the same professional regularly so decisions do not need to be made at the first consultation; *"The advantage of primary care is longitudinality. If they do not want to start today, I explain it, and after two or three months, they might think about it and accept it. (GP-8)"*. In addition, the fact that GPs and nurses generally work as a team and visit the same patients facilitated implementation by ensuring alignment and continuity of care. However, time restrictions and heavy workloads were cited as some of the main barriers by professionals and patients across all organisations; *"I knew time was limited, it is very limited and yes, I would have liked to know a lot more. (Patient-10)"*. Additionally, organisational, cultural and work-environment factors were mentioned. Some professionals recognised being accustomed to a model without patient involvement and sometimes overlooked their inclusion. Moreover, most patients interviewed did not expect the pharmacist to provide health education when dispensing a medication; *"I mean, if the nurse and the doctor do their job, the pharmacist does their job by giving me the pills. (Patient-14)"*.

Finally, at the macrolevel, we anticipated the COVID-19 pandemic would have been an implementation barrier. However, even though professionals reported low motivation after the pandemic, this was not the case.

## DISCUSSION

This process evaluation contributes to understanding how the components of the IMA intervention were implemented, the factors that affected its implementation, its mechanisms of action and its impact on patients' and professionals' behaviours. Improving

adherence through SDM and interprofessional collaboration was considered important to both professionals and patients. The intervention was implemented with adequate fidelity and was generally integrated into clinical practice. However, professionals and patients are not yet fully prepared for this new paradigm of care. Some professionals perceived little distinction between the intervention and usual practice, and some patients preferred the professional to make the final decision.

Effective intervention implementation strategies are crucial for reaching the target population.[44] Training for professionals was considered key in enhancing SDM and learning about the roles of other professionals engaged in patient care. Formal training has been identified as a facilitator in providing professionals with the skills and knowledge needed to engage in and conduct SDM.[45 46] However, consistent with previous research, our findings highlight that a single training intervention may be insufficient, as professionals emphasised the need for continuous training.[45] Furthermore, the literature suggests that insufficient humanistic training may result in professionals lacking essential communication skills, potentially leading them to view SDM merely as a technique, rather than recognising its foundation for effective communication.[46 47]

Fidelity was adequate overall, except for use of the website. The use of decision aids to support SDM has been extensively explored.[48] Leaflets mainly supported understanding of the information rather than encouraging the patient to take part in the decision.[49] Professionals acknowledged applying SDM without the use of decision aids. However, decision aids are known to support patient health literacy and play an active role in risk–benefit discussions, even where patients prefer professional-led decisions.[50] Other web-based studies have revealed that an important implementation barrier is difficulty accessing the tool during the consultation. In our study, this hindered familiarisation with the website and limited its recommendations.[51 52]

Interprofessional collaboration and care standardisation are central to the IMA intervention, especially as the prevalence of chronic diseases increases, necessitating the involvement of the entire multidisciplinary team in making a single decision.[53 54] Although the intervention protocol aligned with professional roles as outlined in healthcare guidelines,[37 55–58] the results showed that roles can be interchangeable in real-life practice. Nurses play a fundamental role in chronic disease care.[59–61] In some PC centres, nurses served as the main patient contact, with interprofessional collaboration acting as a key facilitator. The role of pharmacists in healthcare systems has been widely explored.[62] In the IMA intervention, their role was influenced by the Spanish context, where pharmacies are private establishments of public interest.[37] Although pharmacists recognised their influence on patient behaviour, none reported communication with GPs or nurses, and their role was frequently unclear to other professionals and patients. The role of pharmacists in the IMA intervention requires redefinition. Although community pharmacists are considered health community agents in Spain, they primarily focus on dispensing medications and providing counselling on their use, rather than playing an active role in chronic disease management and health screening.[37] As noted in the previous literature, they are not adequately integrated into the PC model and are often perceived merely as 'vendors'.[38 63–65]

The intervention was considered important and integrated into routine practice, although some professionals perceived no difference between the intervention and usual care, which could indicate low motivation to change practice.[66 67] Although attitudes improved, SDM was sometimes misunderstood as informed decisions rather than an exchange of opinions and decision-making.[68 69] While professionals have expressed a preference for SDM, paternalistic approaches remain deeply ingrained, often limiting conversations about treatment options.[70] Professionals were generally committed to the intervention, as they perceived benefits to the patient and their practice, but organisational integration was hampered by a failure to promote implementation among other professionals. The full integration of SDM into routine practice requires more awareness of patient-centred care models and a broader understanding of the aims and benefits of patient involvement.[66 71]

Patients accepted the intervention and found the leaflets useful for understanding the information provided. Willingness to participate in decision-making varies among patients and should be explored beforehand.[24] However, their views, preferences and context should always be considered when providing treatment recommendations.[24 68 69 72] Some patients appreciated being involved in the decision, while others felt uncomfortable and preferred the GP to make the decision, often not recognising the value of their own experiences and knowledge.[46 73] As highlighted by other authors, adapting SDM to the patient's level of health literacy is crucial for ensuring high-quality care.[74] Moreover, SDM has been recognised for its potential to strengthen patient–professional relationships by viewing the patient as an active agent.[75] This not only reinforces treatment adherence but also fosters a supportive environment that facilitates SDM implementation.[76]

Overall, the adoption of SDM remains limited in clinical practice,[69] and contextual barriers and facilitators need to be considered. As previously described, we identified mainly organisational factors, such as time restrictions and heavy workloads, and patient characteristics, as hindering implementation.[45 71 77] Some of these represent more structural aspects, which require a deeper understanding of the context in order

to enhance the effectiveness of the intervention.[43] Without structural support, SDM risks remaining more of an aspiration than a routine practice in PC. Much progress in SDM has been driven by academia, which often lacks sustainable programmes to integrate it into the system.[78] In addition to increasing professional awareness of patient-centred models, advancing SDM requires the engagement of healthcare managers, inclusion in professional training, and public awareness campaigns.[79] Going forward, prior to implementing an SDM intervention in a new context, it is crucial to assess the local context by engaging stakeholders, understanding organisational structures and evaluating available resources to anticipate potential challenges and guide the development of tailored implementation strategies.

The IMA intervention did not improve adherence[29]; however, SDM remains crucial for enhancing care quality and patient engagement within value-based healthcare. Moreover, SDM is grounded in ethical principles, reinforcing patients' right to make informed choices as a fundamental aspect of professional practice.[80] We believe this alone justifies further discussion on the need for its continued expansion, despite the intervention's limited effectiveness.

### Strengths and limitations

This study provided valuable insights into the implementation of the IMA intervention. It illustrated how different components and contexts interacted and potentially influenced the trial outcomes, using a combination of quantitative and qualitative methods to generate deeper insights. The standardised fidelity and NPT questionnaire used showed adequate validity.

Despite this, there were some limitations. These include potential memory bias from participants, the possible over-representation of responses from professionals who were more actively engaged with the intervention, and patient recruitment being conducted by professionals, which may have led to more positive responses. Furthermore, positively skewed answers might have resulted from interviewers being members of the IMA-cRCT research team themselves. Qualitative interviews were limited to eight PC centres due to logistical constraints, which may have reduced the broader representativeness of all centres. However, the sampling strategy was theoretical and ensured variability based on the centre characteristics and the results of the pre-implementation questionnaire. At last, this study did not capture the experiences of the control group receiving usual care, which hinders the possibility to contrast these with those of the IG.

## CONCLUSIONS

The IMA intervention proved beneficial for both professionals and patients, with adequate fidelity of implementation, and an overall high normalisation into practice. However, additional efforts are needed to embed SDM within PC, as part of the broader shift towards patient-centred care models and continuous improvement of quality of care. This evaluation provided valuable information for the future refinement and expansion of SDM and other complex interventions and for understanding factors influencing SDM in PC.

**Author affiliations**
[1]Health Technology Assessment in Primary Care and Mental Health (PRISMA) Research Group, Parc Sanitari Sant Joan de Déu, Institut de Recerca Sant Joan de Déu, St Boi de Llobregat, Catalonia, Spain
[2]Department of Paediatrics, Obstetrics and Gynaecology, and Preventive Medicine and Public Health, Universitat Autònoma de Barcelona, Bellaterra, Catalonia, Spain
[3]Consortium for Biomedical Research in Epidemiology and Public Health (CIBERESP), Madrid, Madrid, Spain
[4]Department of Medicine, Universitat de Barcelona, Barcelona, Catalonia, Spain
[5]Primary Care Centre Bartomeu Fabrés Anglada, Primary Care Research Institute (IDIAP Jordi Gol), Catalan Institute of Health South Metropolitan Territory Management, Barcelona, Catalonia, Spain
[6]Research Network on Chronicity, Primary Care and Health Promotion (RICAPPS), Barcelona, Catalonia, Spain

**X** Ignacio Aznar-Lou @Ignaznar and Claudia Palma-Vasquez @https://x.com/cpalmavasquez

**Acknowledgements** We thank the professionals and patients who participated and dedicated their time to this study. We thank Alexandra Dima, Anna Fernández Sánchez, Emma Motrico Martínez, Enriqueta Pujol Ribera, Ingrid Vargas, María Luisa Vázquez Navarrete and Edurne Zabaleta for their input on the validation of an instrument to evaluate the IMA intervention. Finally, we thank Stephen Kelly for his help with language editing. This work has been carried out within the framework of the Ph.D. program in Methodology of Biomedical Research and Public Health at the Universitat Autònoma de Barcelona.

**Contributors** MR-V led the initial design and obtained funding for the study. MR-V and CC-P developed the process evaluation protocol and MTP-M, MG-G, IA-L and AS-V advised and contributed to it. All authors were part of the cRCT research team. CC-P led the recruitment, data collection and analysis of quantitative and qualitative process evaluation data. MTP-M, CP-V, MG-G, CG-G, MCO-P and MR-V participated in qualitative data collection and analysis. CP-V led the validation of the questionnaire instrument. CP-V, IA-L, AS-V and MR-V participated in quantitative data analysis. All authors reviewed, clarified and assisted in the interpretation of results. CC-P wrote the first draft of the manuscript and all authors added to and approved the final manuscript. MR-V is the guarantor.

**Funding** This study was funded by the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement Nº 948973). IA-L has a Miguel Servet contract (CP22/00029) funded by the Instituto de Salud Carlos III, MTP-M has the 18th ICS support for the promotion of group research strategies through the intensification of researchers (7Z22/009) funded by the IDIAP Jordi Gol, and CG-G has the 19th ICS support for the promotion of group research strategies through the intensification of researchers (7Z23/018) funded by the IDIAP Jordi Gol.

**Competing interests** None declared.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants. The IMA-cRCT and its integrated process evaluation were approved by the drug research committee (CEIm) at IDIAP Jordi Gol, codeCEIm 21/051-P. Informed consent from the patients was obtained by simplified means in the cRCT. The IMA-cRCT is a low-intervention clinical trial where groups

of subjects are allocated to the intervention groups and which satisfies all the conditions described in paragraphs 2 and 3 of Article 30 of EU regulation number 536/2014. The electronic database used meets all current legal requirements and is encrypted and pseudonymised so that researchers do not have access to data that identifies the patients or professionals. Professionals signed informed consent prior to trial commencement and consented to taking part in the process evaluation. Patients signed informed consent after recruitment and prior to the beginning of interviews. Participants were compensated for their time and travel expenses incurred in participating.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available upon reasonable request. Quantitative and qualitative data and evaluation materials are available from the authors upon reasonable request. Requests to access the datasets should be directed to the corresponding author.



**ORCID iDs**
Carmen Corral-Partearroyo http://orcid.org/0000-0001-9517-4916
Alba Sánchez-Viñas http://orcid.org/0000-0001-5020-7534
Montserrat Gil-Girbau http://orcid.org/0000-0002-4396-6492
Claudia Palma-Vasquez http://orcid.org/0000-0001-8830-1884
Carmen Gallardo-González http://orcid.org/0000-0003-0688-1366
María del Carmen Olmos-Palenzuela http://orcid.org/0000-0003-4078-6717
Maria Rubio-Valera http://orcid.org/0000-0003-2856-1697

## REFERENCES

1 Vrijens B, De Geest S, Hughes DA, *et al*. A new taxonomy for describing and defining adherence to medications. *Br J Clin Pharmacol* 2012;73:691–705.
2 Zeber JE, Manias E, Williams AF, *et al*. A Systematic Literature Review of Psychosocial and Behavioral Factors Associated with Initial Medication Adherence: A Report of the ISPOR Medication Adherence & Persistence Special Interest Group. *Value Health* 2013;16:891–900.
3 Lemstra M, Nwankwo C, Bird Y, *et al*. Primary nonadherence to chronic disease medications: a meta-analysis. *Patient Prefer Adherence* 2018;12:721–31.
4 Cheen MHH, Tan YZ, Oh LF, *et al*. Prevalence of and factors associated with primary medication non-adherence in chronic disease: A systematic review and meta-analysis. *Int J Clin Pract* 2019;73:e13350.
5 Tarn DM, Barrientos M, Pletcher MJ, *et al*. Perceptions of Patients with Primary Nonadherence to Statin Medications. *J Am Board Fam Med* 2021;34:123–31.
6 Gil-Girbau M, Aznar-Lou I, Peñarrubia-María MT, *et al*. Reasons for medication non-initiation: A qualitative exploration of the patients' perspective. *Res Social Adm Pharm* 2020;16:663–72.
7 World Health Organization. Adherence to long-term therapies. Evidence for action. Geneva, 2003. Available: https://iris.who.int/handle/10665/42682
8 Ettehad D, Emdin CA, Kiran A, *et al*. Blood pressure lowering for prevention of cardiovascular disease and death: a systematic review and meta-analysis. *Lancet* 2016;387:957–67.
9 Xu T, Yu X, Ou S, *et al*. Adherence to Antihypertensive Medications and Stroke Risk: A Dose-Response Meta-Analysis. *J Am Heart Assoc* 2017;6:e006371.
10 Bouchard MH, Dragomir A, Blais L, *et al*. Impact of adherence to statins on coronary artery disease in primary prevention. *Br J Clin Pharmacol* 2007;63:698–708.
11 Cutler RL, Fernandez-Llimos F, Frommer M, *et al*. Economic impact of medication non-adherence by disease groups: a systematic review. *BMJ Open* 2018;8:e016982.
12 Derose SF, Green K, Marrett E, *et al*. Automated outreach to increase primary adherence to cholesterol-lowering medications. *JAMA Intern Med* 2013;173:38–43.
13 Fischer MA, Choudhry NK, Bykov K, *et al*. Pharmacy-based interventions to reduce primary medication nonadherence to cardiovascular medications. *Med Care* 2014;52:1050–4.
14 Fischer MA, Jones JB, Wright E, *et al*. A Randomized Telephone Intervention Trial to Reduce Primary Medication Nonadherence. *JMCP* 2015;21:124–31.
15 O'Connor PJ, Schmittdiel JA, Pathak RD, *et al*. Randomized Trial of Telephone Outreach to Improve Medication Adherence and Metabolic Control in Adults With Diabetes. *Diabetes Care* 2014;37:3317–24.
16 Kerner DE, Knezevich EL. Use of communication tool within electronic medical record to improve primary nonadherence. *J Am Pharm Assoc (2003)* 2017;57:S270–3.
17 Aznar-Lou I, Fernández A, Gil-Girbau M, *et al*. Initial medication non-adherence: prevalence and predictive factors in a cohort of 1.6 million primary care patients. *Br J Clin Pharmacol* 2017;83:1328–40.
18 Vilaplana-Carnerero C, Aznar-Lou I, Peñarrubia-María MT, *et al*. Initiation and Single Dispensing in Cardiovascular and Insulin Medications: Prevalence and Explanatory Factors. *Int J Environ Res Public Health* 2020;17:3358.
19 Peñarrubia-María MT, Gil-Girbau M, Gallardo-González MC, *et al*. Non-initiation of prescribed medication from a Spanish health professionals' perspective: A qualitative exploration based on Grounded Theory. *Health Soc Care Community* 2022;30:e213–21.
20 Corral-Partearroyo C, Sánchez-Viñas A, Gil-Girbau M, *et al*. Improving Initial Medication Adherence to cardiovascular disease and diabetes treatments in primary care: Pilot trial of a complex intervention. *Front Public Health* 2022;10.
21 Corral-Partearroyo C, Sánchez-Viñas A, Gil-Girbau M, *et al*. Complex multidisciplinary intervention to improve Initial Medication Adherence to cardiovascular disease and diabetes treatments in primary care (the IMA-cRCT study): mixed-methods process evaluation protocol. *BMJ Open* 2022;12:e067468.
22 Sánchez-Viñas A, Corral-Partearroyo C, Gil-Girbau M, *et al*. Effectiveness and cost-effectiveness of an intervention to

improve Initial Medication Adherence to treatments for cardiovascular diseases and diabetes in primary care: study protocol for a pragmatic cluster randomised controlled trial and economic model (the IMA-cRCT study). *BMC Prim Care* 2022;23:170.
23 Elwyn G, Edwards A, Kinnersley P, *et al*. Shared decision making and the concept of equipoise: the competences of involving patients in healthcare choices. *Br J Gen Pract* 2000;50:892–9.
24 Elwyn G, Frosch D, Thomson R, *et al*. Shared decision making: a model for clinical practice. *J Gen Intern Med* 2012;27:1361–7.
25 Légaré F, Adekpedjou R, Stacey D, *et al*. Interventions for increasing the use of shared decision making by healthcare professionals. *Cochrane Database Syst Rev* 2018;7:CD006732.
26 Saheb Kashaf M, McGill ET, Berger ZD. Shared decision-making and outcomes in type 2 diabetes: A systematic review and meta-analysis. *Patient Educ Couns* 2017;100:2159–71.
27 Mathijssen EGE, van den Bemt BJF, van den Hoogen FHJ, *et al*. Interventions to support shared decision making for medication therapy in long term conditions: A systematic review. *Patient Educ Couns* 2020;103:254–65.
28 Moore GF, Audrey S, Barker M, *et al*. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ* 2015;350:h1258.
29 Corral-Partearroyo C, Sánchez-Viñas A, Aznar-Lou I, *et al*. Effectiveness of a patient-centred complex intervention to improve Initial Medication Adherence to cardiovascular disease and diabetes treatments in primary care (the IMA-cRCT study): a pragmatic cluster randomised controlled trial using Real World Data [Submitted]. 2025.
30 Curran GM, Bauer M, Mittman B, *et al*. Effectiveness-implementation Hybrid Designs: Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact. *Med Care* 2012;50:217–26.
31 Skivington K, Matthews L, Simpson SA, *et al*. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ* 2021;374:n2061.
32 May CR, Mair F, Finch T, *et al*. Development of a theory of implementation and integration: Normalization Process Theory. *Implement Sci* 2009;4:29.
33 Pinnock H, Barwick M, Carpenter CR, *et al*. Standards for Reporting Implementation Studies (StaRI) Statement. *BMJ* 2017;356:i6795.
34 O'Cathain A, Murphy E, Nicholl J. The quality of mixed methods studies in health services research. *J Health Serv Res Policy* 2008;13:92–8.
35 Michie S, Richardson M, Johnston M, *et al*. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Ann Behav Med* 2013;46:81–95.
36 Iniciadores. IMA-cRCT. n.d. Available: https://www.iniciadores.es/
37 Bernal-Delgado E, Angulo-Pueyo E, Ridao-López M, *et al*. Spain: health system review. Health systems in transition. Copenhagen WHO Regional Office for Europe; 2024. Available: https://eurohealthobservatory.who.int/publications/i/spain-health-system-review-2024
38 Rubio-Valera M, Jové AM, Hughes CM, *et al*. Factors affecting collaboration between general practitioners and community pharmacists: a qualitative study. *BMC Health Serv Res* 2012;12:188.
39 May C, Rapley T, Mair F, *et al*. Normalization process theory on-line users' manual, toolkit and nomad instrument. 2015. Available: http://www.normalizationprocess.org
40 Gale NK, Heath G, Cameron E, *et al*. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol* 2013;13:117.
41 McLaren L, Hawe P. Ecological perspectives in health research. *J Epidemiol Community Health* 2005;59:6–14.
42 O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. *BMJ* 2010;341:c4587.
43 Nilsen P, Bernhardsson S. Context matters in implementation science: a scoping review of determinant frameworks that describe contextual determinants for implementation outcomes. *BMC Health Serv Res* 2019;19:189.
44 Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for specifying and reporting. *Implement Sci* 2013;8:139.
45 Waddell A, Lennox A, Spassova G, *et al*. Barriers and facilitators to shared decision-making in hospitals from policy to practice: a systematic review. *Implement Sci* 2021;16:74.
46 Tang C, Wang A, Yan J. Exploring motivations and resistances for implementing shared decision-making in clinical practice: A systematic review based on a structure–process–outcome model. *Health Expect* 2022;25:1254–68.
47 Kunneman M, Gionfriddo MR, Toloza FJK, *et al*. Humanistic communication in the evaluation of shared decision making: A systematic review. *Patient Educ Couns* 2019;102:452–66.
48 Stacey D, Légaré F, Lewis K, *et al*. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2017;4:CD001431.
49 Wieringa TH, Rodriguez-Gutierrez R, Spencer-Bonilla G, *et al*. Decision aids that facilitate elements of shared decision making in chronic illnesses: a systematic review. *Syst Rev* 2019;8:121.
50 Coronado-Vázquez V, Canet-Fajas C, Delgado-Marroquín MT, *et al*. Interventions to facilitate shared decision-making using decision aids with patients in Primary Health Care: A systematic review. *Medicine (Baltimore)* 2020;99:e21389.
51 Peters LJ, Torres-Castaño A, van Etten-Jamaludin FS, *et al*. What helps the successful implementation of digital decision aids supporting shared decision-making in cardiovascular diseases? A systematic review. *Eur Heart J Digit Health* 2023;4:53–62.
52 Jimbo M, Shultz CG, Nease DE, *et al*. Perceived barriers and facilitators of using a Web-based interactive decision aid for colorectal cancer screening in community practice settings: findings from focus groups with primary care clinicians and medical office staff. *J Med Internet Res* 2013;15:e286.
53 Hsiao C-Y, Wu J-C, Lin P-C, *et al*. Effectiveness of interprofessional shared decision-making training: A mixed-method study. *Patient Educ Couns* 2022;105:3287–97.
54 Diouf NT, Menear M, Robitaille H, *et al*. Training health professionals in shared decision making: Update of an international environmental scan. *Patient Educ Couns* 2016;99:1753–8.
55 Coll de Tuero G, Dalfó i Baqué A, de la Figuera Von Wichmann M, *et al*. Guies de pràctica clínica. Hipertensió Arterial. Institut Català de la Salut. Guies pràctica clínica i Material docent. 2012. Available: https://scientiasalut.gencat.cat/handle/11351/4540.2

56 Mata M, Xavier Cos F, Morros R, *et al*. Guies de pràctica clínica. Abordatge de la diabetis mellitus tipus 2. Institut Català de la Salut. Guies pràctica clínica i Material docent. Barcelona, 2013. Available: https://scientiasalut.gencat.cat/handle/11351/4514
57 Verdú Rotellar J, Pacheco Huergo V, Amado Guirado E, *et al*. Guies de pràctica clínica. Insuficiència cardíaca. Institut Català de la Salut. Guies pràctica clínica i Material docent. Barcelona; 2008. Available: https://scientiasalut.gencat.cat/handle/11351/4516
58 Franzi Sisó A, Armengol Alegre J, Baena Díez J, *et al*. Guia de lípids i risc cardiovascular. Institut Català de la Salut. Guies pràctica clínica i Material docent. Barcelona, 2021. Available: https://scientiasalut.gencat.cat/handle/11351/5955.2
59 Gorina M, Limonero JT, Álvarez M. Effectiveness of primary healthcare educational interventions undertaken by nurses to improve chronic disease management in patients with diabetes mellitus, hypertension and hypercholesterolemia: A systematic review. *Int J Nurs Stud* 2018;86:139–50.
60 Martínez-González NA, Rosemann T, Tandjung R, *et al*. The effect of physician-nurse substitution in primary care in chronic diseases: a systematic review. *Swiss Med Wkly* 2015;145:w14031.
61 Hämel K, Röhnsch G, Heumann M, *et al*. How do nurses support chronically ill clients' participation and self-management in primary care? A cross-country qualitative study. *BMC Prim Care* 2022;23:85.
62 WHO Consultative Group on the Role of the Pharmacist in the Health Care System (1988: New Delhi, India)‡, World Health Organization. Pharmaceuticals unit & WHO meeting on the role of the pharmacist: quality pharmaceutical services - benefits for governments and the public (2nd: 1993: Tokyo, Japan). The role of the pharmacist in the health care system: report of a WHO consultative group, New Delhi, India, 13-16 December 1988; report of a WHO meeting, Tokyo, Japan, 31 August - 3 September 1993. 1994. Available: https://iris.who.int/handle/10665/59169
63 Mossialos E, Courtin E, Naci H, *et al*. From "retailers" to health care providers: Transforming the role of community pharmacists in chronic disease management. *Health Policy* 2015;119:628–39.
64 Brewster S, Holt R, Portlock J, *et al*. The role of community pharmacists and their position in the delivery of diabetes care: an update for medical professionals. *Postgrad Med J* 2020;96:473–9.
65 Zardaín E, del Valle MO, Loza MI, *et al*. Psychosocial and behavioural determinants of the implementation of Pharmaceutical Care in Spain. *Pharm World Sci* 2009;31:174–82.
66 Lloyd A, Joseph-Williams N, Edwards A, *et al*. Patchy "coherence": using normalization process theory to evaluate a multi-faceted shared decision making implementation program (MAGIC). *Implement Sci* 2013;8:102.
67 Joseph-Williams N, Lloyd A, Edwards A, *et al*. Implementing shared decision making in the NHS: lessons from the MAGIC programme. *BMJ* 2017;357:j1744.
68 Serrano V, Rodriguez-Gutierrez R, Hargraves I, *et al*. Shared decision-making in the care of individuals with diabetes. *Diabet Med* 2016;33:742–51.
69 Elwyn G. Shared decision making: What is the work? *Patient Educ Couns* 2021;104:1591–5.
70 Driever EM, Stiggelbout AM, Brand PLP. Shared decision making: Physicians' preferred role, usual role and their perception of its key components. *Patient Educ Couns* 2020;103:77–82.
71 Légaré F, Ratté S, Gravel K, *et al*. Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions. *Patient Educ Couns* 2008;73:526–35.
72 Inkeroinen S, Virtanen H, Stolt M, *et al*. Patients' right to know: A scoping review. *J Clin Nurs* 2023;32:4311–24.
73 Joseph-Williams N, Elwyn G, Edwards A. Knowledge is not power for patients: a systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making. *Patient Educ Couns* 2014;94:291–309.
74 Pel-Littel RE, Buurman BM, Minkman MM, *et al*. The influence of health literacy, anxiety and education on shared decision making and decisional conflict in older adults, and the mediating role of patient participation: A video observational study. *Patient Educ Couns* 2024;124:108274.
75 Elwyn G, Lloyd A, May C, *et al*. Collaborative deliberation: a model for patient care. *Patient Educ Couns* 2014;97:158–64.
76 Deniz S, Akbolat M, Çimen M, *et al*. The Mediating Role of Shared Decision-Making in the Effect of the Patient-Physician Relationship on Compliance With Treatment. *J Patient Exp* 2021;8:23743735211018066.
77 Veenendaal H van, Chernova G, Bouman CM, *et al*. Shared decision-making and the duration of medical consultations: A systematic review and meta-analysis. *Patient Educ Couns* 2023;107:107561.
78 Härter M, Moumjid N, Cornuz J, *et al*. Shared decision making in 2017: International accomplishments in policy, research and implementation. *Z Evid Fortbild Qual Gesundhwes* 2017;123–124:1–5.
79 Coulter A. National strategies for implementing shared decision making (Engl.). Gütersloh Ger Bertelsmann Stift; 2018. Available: https://www.bertelsmann-stiftung.de/en/publications/publication/did/national-strategies-for-implementing-shared-decision-making-engl
80 Elwyn G, Tilburt J, Montori VM. The ethical imperative for shared decision-making. *EJPCH* 2013;1:129.