1 ORIGINAL RESEARCH

2	Patient and practitioner views on a combined face-to-face and
3	digital intervention to support medication adherence in
4	hypertension: a qualitative study within primary care
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21 Abstract

Objectives: To explore patients' and healthcare practitioners' views about non adherence to hypertension medication and potential content of a combined very brief
 face-to-face discussion (VBI) and digital intervention (DI).

Methods: A qualitative study (N=31): interviews with patients with hypertension 25 (n=6) and healthcare practitioners (HCPs; n=11) and four focus groups with patients 26 with hypertension (n=14). Participants were recruited through general practices in 27 Eastern England and London. Topic guides explored reasons for medication non-28 adherence and attitudes towards a potential intervention to support adherence. 29 Stimuli to facilitate discussion included example SMS messages and smartphone 30 app features, including mobile sensing. Analysis was informed methodologically by 31 the constant comparative approach and theoretically by Perceptions and 32 Practicalities Approach (PAPA). 33

Results: Participants' overarching explanations for non-adherence were non-34 intentional (forgetting) and intentional (concerns about side-effects, reluctance to 35 medicate). These underpinned their views on intervention components: messages 36 that targeted forgetting medication or obtaining prescriptions were considered more 37 useful than messages providing information on consequences of non-adherence. 38 Tailoring the DI to the individuals' needs, regarding timing and number of messages, 39 40 was considered important for user engagement. Patients wanted control over the DI and information about data use associated with any location sensing. While the DI 41 was considered limited in its potential to address intentional non-adherence, HCPs 42 saw the potential for a VBI in addressing this gap, if conducted in a non-judgemental 43 manner. Incorporating a VBI into routine primary care was considered feasible, 44

45 provided it complemented existing GP practice software and HCPs received46 sufficient training.

Conclusions:

48	A combined VBI-DI can potentially address intentional and non-intentional reasons
49	for non-adherence to hypertension medication. For optimal engagement,
50	recommendations from this work include a VBI conducted in a non-judgmental
51	manner and focusing on non-intentional factors, followed by a DI that is easy-to-use,
52	highly tailored, and with provision of data privacy details about any sensing
53	technology used.
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55	Keywords: medication adherence, qualitative research, high blood pressure, digital
56	intervention, healthcare professional, very brief face-to-face intervention
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66 Strengths and limitations of the study

67	•	To our knowledge, this is among the first qualitative studies to gather patient
68		views on the use of sensing technology such as Wi-Fi or GPS within a
69		smartphone app to support medication adherence.
70	•	The study sought the views of a range of healthcare practitioners on
71		incorporating a very brief intervention for medication adherence into a primary
72		care consultation, a topic not previously explored in-depth.
73	•	The use of stimulus materials provided detailed and focused responses for
74		specific intervention components such as feedback on adherence and content
75		of messages.
76	•	While the sample size was small, the depth and focus of insights gained are
77		sufficiently useful in informing the development and refinement of intervention
78		components.
79		

80 Introduction

Medication adherence, defined as the level to which an individual takes 81 medication as intended by their healthcare prescriber, is a worldwide public health 82 83 concern.[1] Non-adherence to blood pressure lowering medication is estimated at 41%, which is relatively high compared with many other medications.[2, 3] This is 84 associated with increased risk of cardiovascular disease related morbidity and 85 86 mortality.[4, 5] Given that high blood pressure is responsible for nearly 20% of deaths worldwide, non-adherence to antihypertensive treatment is a global health 87 concern.[6] 88

Previous research into medication non-adherence has documented its complexity and multifaceted nature.[7, 8] Two broad categories within this are (i) non-intentional non-adherence, a passive process due to factors not directly within an individual's control, such as memory or access difficulties,[8, 9] and (ii) intentional non-adherence, a more deliberate action whereby an individual makes a conscious decision not to take their medication due to their perceptions about or experiences with their medication or condition.[9]

96 The multifaceted nature of non-adherence presents a challenge to those developing interventions to support adherence; for example, determining which 97 factors to target, while balancing feasibility of delivery with likely effectiveness. Digital 98 99 interventions (DIs) such as SMS text messaging or smartphone applications (apps) offer interactive, low cost and scalable methods of providing support to individuals for 100 101 whom medication adherence is a challenge. DIs are particularly suitable given the 102 increasing use of these by people across the age groups for day-to-day tasks, such as apps for alarm clocks, calendars and shopping lists.[10] In addition, DIs can 103 potentially lower costs compared to traditional face-to-face approaches through 104 reducing or eliminating consultation time required with healthcare practitioners, 105 which may be particularly valuable at times when there is a high demand for 106 consultations e.g. during the current Covid pandemic. [11, 12] 107

Evidence for the effectiveness of DIs in improving medication adherence is promising (e.g. see Thakkar et al [13]). In a recent systematic review of app-based interventions, patients using a smartphone app to support medication adherence for various health conditions were twice as likely to report taking their medications than those receiving usual care.[14] Specific to hypertension, DIs such as SMS messages, smartphone apps, email and Bluetooth blood pressure monitors have

been shown to improve medication adherence and lower both diastolic and systolicblood pressure.[15, 16]

116 Incorporating sensing technology into smartphone apps potentially expands the scope of DIs further. Passive smartphone sensors can collect user location data 117 via GPS or Wi-Fi to enable the delivery of real-time support [17], which is of 118 119 particular relevance given that non-intentional non-adherence is strongly influenced by a person's physical environment.[18] Smartphone sensing technology has shown 120 success in DIs across the domain of health and well-being (e.g. see Cornet and 121 Holden for a review [19]) but user acceptability of such technology in a smartphone 122 app to support medication adherence is largely unknown. 123

124 While user acceptability is key to use of a DI, potential users first need to install and engage with the DI for it to provide benefit. Primary care professionals, 125 such as practice nurses or community pharmacists are ideally placed for 126 encouraging uptake of DIs for medication adherence, for example during a 127 medication review or at the point of prescription collection. A DI used as an adjunct 128 to a face-to-face consultation might therefore be a promising approach to support 129 medication adherence. There is some evidence that DIs combined with tailored tele-130 or web-based feedback from healthcare practitioners, improves adherence to long-131 132 term medication [20] and antihypertensive medication.[21] However, evidence is limited on how healthcare professionals can best promote the uptake of DIs for 133 medication adherence. The acceptability of combining a DI with a very brief face-to-134 face intervention delivered by a healthcare professional to support medication 135 adherence has also not been widely explored. 136

This study aimed to explore patients' and healthcare practitioners' views on i) non-adherence to hypertension medication and ii) a complex intervention designed to support medication adherence. Initial ideas for the intervention consisted of a very brief face-to-face discussion with a primary care provider, followed by ongoing support via a DI (SMS messages or smartphone app). Feedback from participants included preferred content of the intervention and factors likely to influence engagement.

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145 Methods

This study is reported in line with the consolidated criteria for reporting qualitative
 research studies checklist (COREQ)[22], see supplementary file 1.

148 **Design**

We undertook a qualitative study using semi-structured interviews followed by focusgroups.

151 **Recruitment and sampling**

Patients were recruited for interviews from primary care practices based in the 152 East of England (n=3) and East London (n=1). Practices were identified with the help 153 of the Clinical Research Network, an organisation which supports the delivery of 154 research within NHS practices in England. Patients were eligible to participate if they 155 were: 1) prescribed at least one antihypertensive medication for at least the previous 156 three months 2) deemed non-adherent according to GP practice records, with a 157 blood pressure reading of over 140/90 mmHg and/or gaps in filling repeat 158 prescriptions in the previous three months and 3) used either SMS or smartphone 159

apps. The practice administrator at each site generated a list of prospective 160 participants that met criteria 1 and 2, which was screened by a GP or Practice 161 162 Nurse. Eligible patients received a study pack from their GP practice in the post consisting of an invitation letter and participant information sheet. Posters 163 highlighting the study were also displayed in the GP practices. Patients interested in 164 taking part were invited to contact the researcher (MVE) via telephone or email; at 165 166 which point the researcher checked that all three eligibility criteria were met before scheduling an interview. 167

A convenience sample of healthcare practitioners were recruited from the four 168 GP practices taking part in this study. Healthcare practitioners were eligible to be 169 interviewed if they were involved in the care of patients with hypertension e.g. 170 through medication reviews (conducted by a GP, Practice Nurse or Practice 171 Pharmacist) or blood pressure checks and/or health assessments (conducted by a 172 173 Healthcare Assistant). The researcher invited healthcare practitioners to participate during the face-to-face study set-up meeting where they were given a study 174 information pack. The researcher contacted the healthcare practitioners one week 175 later to check willingness to participate and to schedule interviews for those who 176 were interested. 177

Recruitment for focus groups followed that of the patient interviews. To address the low response from eligible patients, the eligibility criteria was widened to include patients prescribed medication for type 2 diabetes, as research indicates similar rates of medication non-adherence and barriers to adherence as for hypertension.[23, 24] The eligibility criteria was also narrowed to ensure that participants were familiar with using smartphone apps (i.e. SMS alone was not sufficient). The decision to cease individual interviews and switch to focus groups

with patients was due to preliminary analysis from the interviews adding little new
information to findings from previous research, and our experience of the usefulness
of focus groups to gain feedback on the format, content and structure of DIs. [25–27]

188 Data collection

Patient interviews were conducted by one researcher (MVE) at patients' home, workplace or local library. Healthcare practitioner interviews were conducted at their place of work by the same researcher (MVE). Focus groups were conducted at community centres local to the patients' general practice and moderated by two researchers (MVE and JJ).

Interviews and focus groups were guided by flexible topic guides [28] 194 developed by the research team, drawing on the Perceptions and Practicalities 195 196 Approach (PAPA) framework [18] and previous research experience in both the topic area and intervention development. Topic guides were reviewed by Patient and 197 Public Involvement (PPI) representatives to ensure the questions were easy to 198 understand and appropriate for the study objectives. Broadly, interview topics 199 included: reasons for medication non-adherence, current practice of HCPs during 200 201 medication-related consultations, and views on a potential SMS text message or smartphone app intervention that could support adherence. Example intervention 202 content included medication reminders, advice and support messages, and feedback 203 on adherence. See supplementary file 2 for the topic guides and example DI content. 204 HCPs were shown an example protocol for a very brief face-to-face discussion or 205 'VBI' to generate discussion (see supplementary file 3). Components of the VBI 206 included: introducing the digital support to the patient and inputting basic patient 207 information via an online questionnaire to generate the tailored digital support. 208

Focus groups followed similar topic guides to the interviews, focusing on attitudes towards smartphone apps in particular, including the acceptability of sensing technology such as location sensing. To prompt discussion and gain feedback, both interview and focus group participants viewed stimulus materials of example intervention messages, including medication reminders, and smartphone app features, including graphs and images (see Figure 1 for examples).

Written informed consent was taken in person by the researcher immediately prior to the interviews and focus groups commencing. All patients received a £20 voucher for taking part. Interviews and focus groups were audio-recorded and professionally transcribed verbatim. Interviews lasted on average 47 minutes and focus groups 1 hour and 28 minutes.

220 Data Analysis

Analysis was informed methodologically by the constant comparative 221 approach[29] and theoretically by the Perceptions and Practicalities Approach 222 (PAPA), which incorporates and acknowledges the blurring of and distinction 223 between intentional and non-intentional non-adherence.[18] Interview transcripts 224 225 were read and re-read to aid familiarisation and identify preliminary themes; these broad descriptive themes were formed into an initial coding framework related to 226 barriers and facilitators to medication adherence and a potential intervention. Each 227 228 transcript was then coded systematically (MVE) using NVivo gualitative dataindexing software (version 12; QSR International) and the coding framework was 229 refined throughout the process. The process was repeated for focus group 230 transcripts; the coding framework was further expanded and refined, given the 231 additional topics explored in the focus groups. A sample of interview and focus group 232

transcripts were independently coded by a second researcher (JJ) to confirm and
strengthen the validity of findings. Meetings between the research team (MVE, JJ,
HE) facilitated data analysis including discussion of themes, sub-themes and the
interrelationships.

237 Patient and public involvement

All study materials (participant information sheet, invitation letter, study poster, 238 consent form, topic guides and stimulus materials) were reviewed by representatives 239 from the Cambridge University Hospitals Patient and Public Involvement (PPI) panel. 240 We made a number of changes to the study materials as a result of PPI input: 241 adjusted the language to make the documents more accessible and ensured 242 interview questions were sensitively worded and easy to understand from a patient 243 244 perspective. PPI representative Jennifer Bostock provided input throughout the study and reviewed and commented on this manuscript. 245

246 Ethical approval

Ethical approval for this study was obtained from the West Midlands – Solihull Research Ethics Committee, as part of NHS Health Research Authority approvals (Reference: 18/WM/0050).

250

251 **Results**

Of the 126 eligible patients prescribed medication for hypertension who were sent an invitation, six were interviewed. All 11 healthcare practitioners approached by the researcher were deemed eligible and agreed to take part. Of the 218 patients prescribed medication for hypertension and/or type 2 diabetes who were then sent

an invitation to a focus group, 14 participated (four focus groups with 3-5 patients per
group). Recruitment of participants to focus groups continued until no new themes
were emerging in relation to the specific topics covered.

Patient participant characteristics are reported in Table 1. Their mean age 259 was 62.7 years (range 47 – 79 years), 60% identified as male and 85% as White 260 261 British. Eighty percent of patients reported using both SMS and smartphone apps, with the remaining 20% using SMS text messages only. All patients self-reported 262 having occasionally missed or skipped their medication in the previous 3 months. 263 HCP participant characteristics are reported in Table 2; six Practice Nurses, two 264 Healthcare Assistants, two Practice Pharmacists, one GP. Participants were 265 recruited from four GP practices based in urban (n=3) and rural (n=1) locations. GP 266 practice Index of Multiple Deprivation (IMD) scores, a measure of relative socio-267 economic status in England based on postcode, ranged from 'least deprived' (n=2), 268 to 'less deprived' (n=1) and 'more deprived' (n=1), see Table 2. 269

270

271 **Table 1** Participant characteristics (patients)

Characteristics	(n)	%
Gender		
Female	8	40
Male	12	60
Age (years)		
41-50	2	10
51-60	4	20
61-70	11	55
71-80	3	15
Ethnicity		
Asian or Asian British – Indian	1	5
Asian or Asian British – Pakistani	1	5
Black or Black British – Caribbean	1	5
White British	17	85

Phone use SMS only SMS and smartphone app	4 16	273 20 ⁷⁴ 8975	Note: n=20
Data collection method Semi-structured interview Focus group	6 14	276 30 70 277	

Table 2 Participant characteristics (healthcare practitioners) and GP practice

demographics

Characteristics	(n)	%	281
Healthcare practitioners Job role			282
General Practitioner	1	9	283
Healthcare Assistant	2	18	
Practice Nurse	6	55	284
Practice Pharmacist	2	18	285
			285
Gender	10	04	200
Female	10	91	287
Male	1	9	
Years practising			288
≤10	5	46	289
11-20	2	40	205
21-30	2	18	290
≥31	2	18	291
_01	E	10	291
GP practices			292
GP practice location			
Urban	3	75	293
Rural	1	25	294
GP practice IMD quintile			295
First quintile (least deprived)	2	50	
Second quintile (less deprived)	1	25	296
Fourth quintile (more deprived)	1	25	297
, ,			231
			298

Note: Healthcare practitioner n=11, GP practice n=4, IMD = Index of Multiple Deprivation,

which ranks every small area in England from 1 ('most deprived area') to 32,844 ('least deprived'). IMD scores of the 4 GP practices in this study: 9924, 25270, 26871, 30807.

To present the findings, we broadly categorise the key themes identified into the following categories: reasons for non-adherence, recommendations for message content, tailoring the digital intervention, acceptability of sensing technology, and attitudes towards a VBI. We provide illustrative quotes below. See supplementary file 4 for additional quotes from participants. For reference, 'digital intervention' (DI) refers to both SMS text messages and smartphone app, as the same intervention messages can be delivered using both formats.

310 Reasons for non-adherence

- Participants provided two key explanations of non-adherence to antihypertensive
- medication. First, for *non-intentional* non-adherence, forgetting was the most
- 313 common reported reason and was mentioned in three ways: forgetting to take
- medication, forgetting whether or not medication had been taken and forgetting to re-
- 315 order the prescription in time.

- Sometimes you can't remember whether you have taken them already. And that can be problematic, so if someone asks you, you think, 'well, I don't know, maybe I have, maybe that was yesterday.' [P04, male, 40s]
- 320 Second, in terms of *intentional* non-adherence, the experience or anticipation of side
- 321 effects was a reason given for skipping, altering or delaying medication, as was the
- 322 general reluctance to be reliant on medication.
- I wish I could live without medication, I hate pumping my body with drugs.
 Sometimes I wonder, 'what side effects am I gonna have with this? Is it really
 benefitting me?' [P06, female, 60s]
- A lot of patients [...have said], 'yes, the doctor has changed my medication, but they make me go funny, so I'm just going to take half or I'll just crush that and just take half instead of the two.' [HCP 05, Healthcare Assistant, female]
- 329330 These overarching explanations were apparent when participants discussed the
- 331 merits of a digital intervention to improve adherence, as presented in the following
- sections. We begin with participants' views about a DI's messaging content, followed

- by tailoring and then sensing technology; the final section considers the role of the
- VBI component.

335 **Recommendations for message content**

- 336 Simple reminder messages were perceived as useful for both taking medication and
- re-ordering prescriptions.
- Even if I'm in a hurry, [when] I receive this reminder I [would] realise the importance. I think if I keep getting messages that would be very effective and definitely help me. Even if I'm tired and it would make me [...] I'd force myself to get up and go and take the medication. [P06, female, 60s]
- It would be useful, if you're running out of tablets, to have some way of
 automatically reordering or a reminder to do that. So it's reminding you to take
 your tablets, and also when you're running low. [P04, male, 40s]
- Information-giving messages were only perceived as helpful by participants if
- 348 providing advice when medication had been missed, for example the safest way to
- 349 'catch up' on a missed dose.

There ought to be a button of 'I've forgotten them 'til now, which bits should I take?' That could be useful. [FG3, male]

352

346

353 While HCP-participants recommended messages about the benefits of medication or

- the consequences of non-adherence, patient-participants considered these unhelpful
- and unnecessary, particularly if lack of knowledge was not a barrier to adherence.
- I know what the risk is [from not taking my medication]. I don't feel that I want it repeated, no. [P03, male, 60s]
- 358 There was, however, some recognition that newly-diagnosed patients may find such
- 359 information motivating:

If you're new to taking blood pressure tablets [information on consequences of non-adherence] would be good. I mean, us experienced people who've taken them for years most probably don't need reminding that if you don't take it,

- something serious is gonna happen to you. [FG3, male]
- 364

- 365 The idea of receiving feedback on one's adherence, generated from self-report via
- 366 SMS message or App, in a message of encouragement (e.g. *'Well done!'*) was
- viewed as unnecessary. Participants were more receptive to schematic feedback in
- the form of a graph, score or percentage.

Some people might need that encouragement, but then again, it sounds a bit patronising to some people, doesn't it [laughs]? [...] I think the percentage thing would give people pride, you know, 'oh, I've reached 100% [of taking my medication] this month, I feel really good about that'. Once a month I'd like to know what my score was for the month. I think that would probably be enough incentive for me personally. [P03, male, 60s]

- 375
- 376 Regular smartphone users suggested that feedback in the form of a monthly
- 377 calendar highlighting 'missed medication' days, could be useful for spotting a pattern
- and identifying the circumstances of those days that contributed to a missed dose.
- 379 Moreover, participants suggested the potential for this to facilitate discussion with a
- 380 healthcare professional too:

A: I think [the app] would also be good to take, when you have a medication
review, to take to your GP so he or she can see what's going on as well.
B: Yeah, help fix it by doing something, yeah
[FG3, male (A, B)]

- 385
- 386
- 387 **Tailoring the digital intervention**
- Participants commented how they would be more likely to use, and continue to use,
- the DI if the messages were tailored to their preferences and their individual
- 390 medication regime, in terms of frequency and timing of doses:
- Some people are on medication once a day, twice a day, three, four. Could the app be tailor-made for the individual? And remind us accordingly? [FG2, female]
- 394 A: That's why [the intervention] should be tailor-made for the individual
- 395 patient. I think it's going to be critical really. Rather than a generic –
- 396 B: And have options, yeah.
- A: Because if it's a generic app and it doesn't suit some people they won't use it or they won't respond to it. [FG1. male (A.B)]

- 399
- 400 Participants noted the importance of the DI including *all* their prescribed medications,
- 401 i.e. not just the hypertension ones.
- 402I think it would need to be somewhat of a select or deselect, you know, 'take403all' but you can un-tick the ones that you're not taking now. [FG4, female]
- A: I would do it as all one. Even if you're doing it principally motivated by blood
 pressure, in the sense it's, you're trying to remind us to take pills in general,
 aren't you, so you have to somehow-
- 407 B: Yes, I think you want all of them there. [FG3, male (A), female (B)]
- 408
- To ensure that tailoring meets patients' preferences and medication regime, and the
- changes over time, participants highlighted the importance of patients having control
- 411 over the DI's settings. For example, being able to change timings of reminders and
- 412 adding in short term medication.
- 413A: I think I'd like to put my own [medications] in. And then when you have a414"short course" [of medication] as we say, I'll add that in as well. I'd rather be in
- charge of putting it in.
 B: Especially as some you have to have on an empty stomach, don't you?
 A: Yeah, so you could fiddle with your timings for that one. [FG2, female (A),
 male (B)]
- 419
 420 It's gotta be a dynamic thing. Medications change, dosages change, things
 421 get stopped, times may change, so I probably would see as an app which
 422 patients would be free to add and subtract. [HCP 02, GP, male]
- 423
- 424 A 'snooze' function (similar to an alarm snooze) was well-received by participants,
- 425 provided users could set their own parameters, e.g., length of snooze duration and
- 426 maximum number of snoozes.
- It would be good for me 'cos I'm often not home when I'm supposed to take
 them, so if you hit the 'snooze' for an hour or whatever you choose it to be,
 [...]and it'll keep reminding me again and I'll take the tablets [when I'm home].
- 430 [FG1, male]
- 431
- 432

A suggestion for tailoring by adding images of medications into the app raised more 433

problems than benefits; participants pointed out that "every time you get the 434

medication, the box changes" [FG1] and it was felt this would create confusion, 435

rather than help. 436

437

Acceptability of sensing technology 438

Participants were initially wary about the incorporation of sensing technology, such 439

as GPS or Wi-Fi to determine location, into an app. They raised concerns about 440

surveillance, typically referred to as "Big Brother" [FG1, FG3] watching them. 441

Participants were more likely to accept sensing technology if the perceived benefits 442

(such as tailoring medication reminders to their specific schedule and locations) 443

outweighed concerns about data privacy. 444

It would make it impossible to forget 'cos I'd just walk through the door and 445 take 'em. That would be brilliant. [FG1, male] 446

447

Participants requested information to address these concerns, including: who has 448

access to their data beyond the university (in particular, less trusted organisations 449

- such as insurance or marketing companies), where data are stored, and what 450
- happens in the event of hacking. 451
- A: Who are you gonna share this with? That's all I'm worried about [...] 452 B: It could be pretty valuable information for insurance companies to put their 453 premiums up. [FG4, male (A), female (B)] 454 455 I think it'd be more reassuring to know it was a medical body behind it or a 456 university body behind it; it gives it some substance and credibility. [FG1, 457 male] 458 459 Participants wanted to retain personal control over the sensing function, with the 460
- 461 ability to choose when the app tracks and records their location data as well as the

ability to opt in/out at any point.

- I think it would be a case of opt-in because I think some people would think it
 an invasion of privacy. I mean, personally I think it's a good idea but, you see,
 some people wouldn't like it. [FG4, female]
- 467 Discussions about sensing technology prompted participants to suggest further ideas
- 468 for functions of an app. Participants in two focus groups suggested linking the
- sensing technology with the smartphone calendar, to proactively detect periods
- 470 when away from home, triggering reminder messages to pack medication or re-order
- 471 prescriptions.

472 The app ought to be able to detect [that] my calendar says, 'Away for the 473 weekend.' So the app could say, "Ooh look, you're going away for the 474 weekend" it could send me a message or something on the Friday to make

- sure I pack them. That's almost what I want to be reminded of. [FG3, male]
- 476

466

- 477 Participants emphasised the need for additional features to be optional, recognising
- that over-complicating the DI risked disengagement from potential users.
- I suppose it's a case though of getting sufficient ability to customise it against
 making it just too longwinded and complicated for people to be bothered.
 [FG4, female]
- I'm just trying to think of just the least steps possible for the patient, because
 just adding more things is going to make them less likely to use these sorts of
 things... It needs to just be easy for them. [HCP 01, Practice Pharmacist,
 female]
- 487 Above all, participants emphasised the importance of the DI being user-friendly for
- the target group, many of whom may be less familiar with smartphones.
- 489 The caveat I suppose might be that those that tend to have the chronic
- diseases tend to be the older age group so they may not be so tech savvy.
 We've got some patients who don't use mobile phones even now. [HCP 02,
- 491 492

GP, male]

493

- 494 495
- Attitudes towards a very brief face-to-face intervention (VBI)

- 496 Patient-participants' discussions about the DI functions largely focused on
- 497 addressing non-intentional non-adherence mainly forgetting. On the whole, they
- 498 were sceptical about a DI's success in addressing intentional non-adherence:
- 499 If they're not taking the tablets and they don't wanna take the tablets, why 500 would they sign up for the app? [FG1, male].
- 501 HCP-participants suggested including messages encouraging users to contact their
- 502 healthcare provider if experiencing problems with their medication.

503 That would be really useful in that if they're stopping it for any reason it needs to 504 come up with a message to say, "Please make an appointment with your GP. 505 There may be alternative medications available which would suit you and you 506 need to make an appointment to discuss that". [HCP 03, Practice Nurse, female] 507

- 508 However, a more promising way of addressing intentional non-adherence was
- 509 highlighted in relation to the 5-minute VBI component prior to use of the DI. The VBI
- 510 was presented as a way for HCPs to signpost patients to the DI and discuss
- 511 medication taking behaviour. HCPs talked positively about how, if done in a non-
- 512 judgemental way and by an HCP with an established rapport with the patient, this
- 513 could foster open communication and a more constructive consultation.

514 That's the important thing, when patients can relate to you and they can see 515 that you're actually not judging them, they do tend to then engage better.

- 516 [HCP 07, Practice Nurse, female]
- 517 A key aspect of encouraging honest communication in the VBI would be
- acknowledging that it is acceptable to have concerns about being prescribed
- 519 medication. HCPs recommended asking the patient to talk through these concerns
- and, if needed, book a follow-up consultation with a prescribing practitioner about
- 521 changing medication.

522 Have a discussion with them as to what's been happening, what the issues are, 523 how we can make it easier for them [...] 'Is there a problem with it? Are you 524 getting side-effects? Do you find it difficult to take?' And then we can explore 525 some of the issues. What is really important is to sift through what the issues

- are. Our role in the face-to-face is actually we can explore some of these things
 a bit easier. [HCP 06, Practice Nurse, female]
- 528
- 529 All HCPs perceived the VBI element as feasible to deliver within primary care,
- recommending incorporating it alongside a medication review or blood pressure
- 531 check. HCPs had two key provisos: training to help them deliver the VBI within the
- tight timing of five minutes, and a "*user-friendly*" template that could be incorporated
- 533 in existing computer systems for inputting patient data to inform the subsequent DI.
- 534 HCPs also noted the need for sufficient training in using the DI itself, given their role
- in encouraging its use in their patients following the VBI.

536 I think that will be important, that whoever is talking about the app needs to 537 know how it works and how you use it... Because if somebody who is 538 recommending it doesn't know how to use it then you're not gonna buy into it. 539 [HCP 09, Practice Nurse, female]

540

542	
543	Discussion
544	Summary of main findings
545	Patients prescribed antihypertensive medication and the healthcare
546	practitioners that care for them, highlighted nonintentional (forgetting) and intentional
547	(side-effects, reluctance to medicate) reasons for their non-adherence. Participants
548	found a mobile digital intervention (DI) that provided simple medication reminders
549	and feedback messages acceptable. To facilitate engagement with the DI,
550	participants recommended it was tailored to the needs of the individual and their
551	medication regime as well as providing user control over the tailoring and other
552	optional functions. The use of sensing technology within a smartphone app was
553	acceptable to participants provided they received comprehensive information about
554	the associated use and confidentiality of their data.
555	While the DI was considered limited in its potential to address intentional non-
556	adherence, HCPs saw the potential for a brief face-to-face discussion (or 'VBI') with
557	patients in addressing this gap, when delivered alongside a DI. Incorporating a VBI
558	into a routine primary care was considered feasible, if it could be integrated into
559	existing practice software systems and if training were provided.
560	Strengths and limitations of the study

561 Drawing on relevant theory, [8, 9, 18] this study was conducted as 562 development work with a target patient group to inform aspects of an intervention as 563 part of a larger research programme.[30] Whilst previous research has investigated 564 the use of sensing technology and smartphone apps for health, [19] this study is 565 among the first to gather qualitative data on the acceptability of such technology (e.g.

Wi-Fi or GPS) in a smartphone app designed to support medication adherence (see
also Kassavou and colleagues [31]). Whilst advances in technology can provide
additional features to smartphone apps, it is important to assess the intended user
group's views of such technology before its implementation.[32]

We gained insights from a range of healthcare practitioners on the 570 571 acceptability and feasibility of incorporating a VBI for medication adherence into a primary care consultation, a topic that has not been previously explored in-depth. 572 The recommendations arising from our findings can inform the development and 573 implementation of a medication adherence VBI in primary care. Developers should 574 consider the following: the importance of the practitioner-patient relationship when 575 discussing medications, exploration of patient-specific barriers to adherence, 576 templates embedded within existing GP practice systems, and sufficient training for 577 HCPs. 578

579 The use of stimulus materials generated discussion in the interviews and 580 focus groups, and provided focused responses for specific hypothetical intervention 581 components.

We acknowledge that this is a small-scale qualitative study, where 85% of the patient sample were White British and 91% of the healthcare practitioner sample were female. As such, the findings may be limited in their application to a patient and healthcare professional population. However, the depth and focus of insights gained provided rich data that were sufficiently useful in informing the development and refinement of intervention components for the wider programme, and to similar interventions.

We experienced challenges with recruiting patients through GP practices, particularly 589 those who were non-adherent to their medication, a group who may be less likely to 590 591 participate in a study of this nature. For future studies we would recommend widening recruitment methods to include patients not tied to a specific sample of GP 592 practices, e.g. via social media channels or community groups. We acknowledge the 593 possibility that patients who are intentionally nonadherent to their medication may be 594 595 unwilling to download an adherence app or receive SMS support messages. In these instances, alternative, more intensive intervention methods involving multiple BCT 596 597 components may be considered appropriate, such as motivational interviewing delivered face-to-face and/or over the telephone.[33-35] 598

599

600 Comparisons with existing literature

The findings echo previous research that has identified the main reasons for non-adherence to cardiovascular-related medication as forgetting and side-effects, [24] [36] as well as the broad categorisation of reasons into intentional and nonintentional.[37, 38] In our study, this distinction was particularly helpful when considering which elements of an intervention were appropriate for targeting these two broad categories.

Participants with lived experience of hypertension saw little value in information-style messages (e.g. about the consequences of non-adherence) in addressing intentional non-adherence. Rather, they suggested that such messages may be most helpful for newly diagnosed patients. This follows previous qualitative research in which mHealth interventions were deemed especially appropriate for "newbies" [39] i.e. patients with less experience in managing a health condition

compared to those with established medication routines, for atrial fibrillation [40] and 613 type 2 diabetes. [39] Similar to previous studies [26], participants expressed 614 615 concerns about receiving too many messages, suggesting this would influence (dis)engagement with the DI. Participants also emphasised the need for a DI to be 616 as simple and easy-to-use as possible, another common theme in usability studies 617 for medication adherence DIs, whereby difficulties with navigating a website, SMS or 618 619 smartphone app have presented barriers to usage.[41, 42] A related concern is the potential burden that self-monitoring DIs place on the user, for example, asking 620 621 patients to self-report their medication taking behaviour within a set timeframe.[43, 44] Our findings support the need for usability testing with the DI target users, which 622 could include assessing any associated burdens or extra responsibilities placed on 623 the user. 624

625 Participants in this study saw the benefit that sensing technology could 626 provide but raised data privacy concerns about its use within a medication reminder smartphone app, requesting comprehensive information and user control. Similar 627 concerns have been identified in previous research into location-sensing apps. For 628 individuals living with HIV, the acceptability of location-based self-monitoring 629 reminders was dependent on the purpose of the app and who would have access to 630 their data [45]. Similarly, young adults in Dennison [46] worried about the storage of 631 personal location data collected by health apps and wanted control over 632 personalising the app settings. 633

Despite the privacy concerns, participants in this study viewed a locationsensing smartphone app more favourably if it was created by a university or charity rather than a commercial company. This follows user feedback of other locationbased apps for smoking cessation, [47] medication adherence [31] and mental

health, [48] in which apps designed by universities or for research purposes were
deemed more trustworthy by participants. This reflects the discourse around the
ethics of mHealth, whereby third parties and insurance companies pose potential
threats to the safety of patients' health data collected by sensors or smartphone
apps.[43] These ethical considerations are of particular importance given the rise of
mHealth in the healthcare sphere.

644

645 **Recommendations for an intervention to support medication adherence**

The findings from this study have several implications for the development of 646 a DI to support medication adherence. To encourage engagement with an 647 intervention, it needs to be highly tailored to each individual. This includes: the timing 648 and content of reminder messages (to address non-intentional non-adherence) and 649 the content of support messages (for intentional non-adherence), where knowledge 650 and duration of health condition varies between individuals. Furthermore, a key 651 tailoring variable as recommended by HCP-participants was the individual patient's 652 specific barrier(s) to adherence. Tailoring data can be collected using various 653 methods, ideally before the start of the intervention for optimal impact. This could 654 include a short questionnaire, in person or by phone with a practitioner, within a 655 smartphone app, or via a set of SMS messages requiring responses.[26] 656

It was common for participants in this study to be taking multiple medications
per day, and most wanted this to be reflected in the medication reminders. This
requires a balance between providing appropriate adherence support without overcomplicating the DI or overburdening the user, resulting in reduced intervention
engagement.[49]

This study obtained novel insight from patients on the use of passive sensing 662 technology within a medication adherence smartphone app. To increase the 663 664 acceptability of sensing technology, future apps should explain the benefits that it can provide to the user, such as tailored medication reminders based on real-time 665 location, or prompts to pack medication for upcoming holidays detected via calendar 666 syncing. The app must provide a flexible opt in/out option for the collection of 667 668 sensing data as well as information on how personal data will be used and stored within the app. Lastly, users may be more accepting of a location-sensing app 669 670 created by a university or charity rather than a commercial company.,

Primary care was viewed as an appropriate setting for HCPs to introduce 671 patients to a DI and pair it with a brief behavioural face-to-face discussion, or 'VBI'. 672 More specifically, this could address intentional non-adherence by exploring the 673 specific barriers to medication adherence with patients. Using a non-judgemental 674 675 approach for this, would encourage patients' openness, which in turn would provide more useful information for tailoring the DI and possibly making adjustments to the 676 all patient's regime as part of the usual care. This supports a body of literature on 677 shared decision-making [50] which has demonstrated an association between an 678 improved patient-professional partnership and medication adherence, for a variety of 679 conditions [51] and for hypertension specifically.[50, 52] Delivering a VBI requires 680 skill, in order to incorporate all elements and within the short timeframe.[53, 54] Our 681 findings indicate the importance of comprehensive training for healthcare 682 professionals which incorporate the principles of shared decision-making and the 683 skills to deliver the intervention in under five minutes, as well as proficiency in using 684 a DI. Lastly, the template for HCPs to complete the VBI and/or enter patients' details 685

into the DI should be user-friendly and embedded into existing GP practice softwaresystems.

688

689 Conclusion

Overall, patients and healthcare practitioners saw the benefit of receiving 690 medication reminders via SMS message or smartphone app. Intervention developers 691 should consider an intervention that is highly tailored to the user, straightforward to 692 use, and addresses data privacy concerns. The use of sensing technology in an 693 694 adherence support smartphone app was acceptable to patients, therefore future research could investigate the feasibility of incorporating such technology into a 695 smartphone app for adherence. A routine primary care consultation was viewed as 696 697 an appropriate setting to introduce the DI to patients and discuss medication-taking behaviour with patients, but the feasibility of delivering it as 'very brief' i.e. under five 698 699 minutes, should be explored further.

700

701 Supplementary material

- 702 S1 COREQ checklist
- S2 Topic guides and sample of proposed intervention content
- 704 S3 Example VBI protocol
- 705 S4 Extra participant quotations

706

707 Figure 1 (legend)

Example digital intervention content to generate discussion in interviews and focus 708

groups; medication reminder notification, feedback on medication adherence levels 709

710 (weekly and monthly), SMS support message

711

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Author contributions 727

726

All authors made substantial contributions to the conception and design of the study. 728

MVE conducted the interviews, co-facilitated the focus groups, conducted data 729

analysis and drafted the manuscript. JJ co-facilitated the focus groups, contributed to 730

data analysis and drafted the manuscript. HE provided supervision and guidance for 731

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741 **Competing interests**

742 None declared.

743 **Ethics approval**

- This study was approved by the West Midlands Solihull Research Ethics
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747 Data availability statement

- 748 Data are available upon reasonable request from the corresponding author.
- 749 Abbreviations: COREQ, consolidated criteria for reporting qualitative research; DI,
- digital intervention; GP, general practitioner; HCP, healthcare practitioner; IMD,
- ⁷⁵¹ Index of Multiple Deprivation; NHS, National Health Service; NIHR CRN, National
- Institute of Health Research Clinical Research Network; VBI, very brief intervention.

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