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Recruiting patients into a digital behavioural intervention in general practice: insights from the ENERGISED trial

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Abstract

Background: Recruiting patients into randomised controlled trials in general practice is challenging and carries a substantial risk of bias. The ENERGISED trial evaluated a digitally supported behavioural intervention to increase physical activity in patients with prediabetes or type 2 diabetes recruited through general practice. To minimise bias, the trial employed a systematic recruitment strategy where general practitioners assessed patient eligibility from random stratified samples of their registers and sought consent from those deemed eligible. This study aimed to analyse the ENERGISED trial's recruitment process and identify sources of potential bias arising from general practitioners' eligibility assessments (selection bias) and patient consent (self-selection bias).

Methods: Patients with prediabetes or type 2 diabetes were randomly sampled from the registers of 28 Czech general practices using sex- and diagnosis-stratified lists. Eligibility was systematically assessed during routine practice visits, with general practitioners documenting reasons for ineligibility. All eligible patients were invited to participate, and reasons for non-consent were recorded. Logistic mixed-effects models were used to examine the influence of patient characteristics (age, sex, diagnosis) and general practitioner characteristics on eligibility and consent.

Results: Of 1,376 sampled patients, 1,138 (83%) were assessed, 792 (70% of assessed) were eligible, 348 (44% of eligible) consented and 343 were randomised. Older age was associated with lower odds of eligibility (OR 0.955, 95% CI 0.942–0.968; $p<0.001$) and lower odds of consent among eligible patients (OR 0.972, 95% CI 0.958–0.986; $p<0.001$). Ineligibility was most often due to digital barriers (227 cases, 44.6% of ineligible). Practices with older registered populations showed stronger age-related bias. Female practitioners and practices with more diabetes/prediabetes patients achieved significantly higher eligibility rates.

Conclusions: Systematic recruitment through general practice can reduce selection and self-selection bias, yet digital exclusion, particularly in older adults, persists. Future trials must proactively address digital literacy and age-related barriers to ensure representative participation in digital health research.

Keywords: Clinical trial recruitment; Primary care; Type 2 diabetes; Physical activity; Selection bias; Digital exclusion; mHealth

Background

Recruiting patients into randomised controlled trials conducted in general practice remains a persistent challenge. Despite the increasing prevalence of chronic metabolic disorders such as type 2 diabetes and prediabetes, and their routine management in primary care, clinical trials often struggle to enrol representative patient populations. Recruitment may be hindered by a combination of practice-level workload constraints, trial-specific eligibility criteria, and patient-level barriers, including digital literacy, health beliefs, and functional limitations. These factors can introduce selection and self-selection bias, threatening both the internal and external validity of trial findings [1,2,3].

The ENERGISED trial evaluated a pragmatic digitally supported behavioural intervention to increase physical activity among adults with prediabetes or uncomplicated type 2 diabetes, recruited through general practice. The intervention incorporated self-monitoring with a wrist-worn Fitbit tracker, phone counselling, and a digital support platform using just-in-time adaptive text messaging (JITAI), integrated into routine primary care across multiple sites in the Czech Republic. Comparable trials have shown that digital interventions for people with type 2 diabetes and prediabetes require intensive and flexible recruitment strategies to meet targets and maintain equity [4,5,6]. For example, previous studies of physical activity interventions in primary care identified a selection bias when general practitioners (GPs) preferentially pick those patients whom they believed to be able to use (e.g., highly educated patients) and to benefit from the intervention (e.g., patients with overweight and obesity) [7, 8]. To tackle this, the ENERGISED trial implemented a systematic recruitment procedure that limited GPs' discretion by using randomised, stratified patient lists generated from electronic health records. This approach aimed to minimise selection bias and ensure a more representative sample across age, sex, and diagnosis groups. Self-selection bias may occur when patients decline participation due to personal reasons—such as time constraints, discomfort with digital tools, or low perceived benefit—potentially limiting the representativeness of the sample [9].

To evaluate how this recruitment strategy worked in practice and to examine potential sources of selection and self-selection bias, we analysed recruitment data from the ENERGISED trial. Specifically, this study quantified recruitment flow from initial patient identification to randomisation, explored the influence of patient and GP characteristics on eligibility and consent, and investigated patterns of exclusion, which have not been examined in previous ENERGISED publications. By disentangling the drivers of recruitment attrition in a real-world setting, our findings provide practical and methodological insights to inform the design of future primary care trials—particularly those evaluating behavioural interventions involving digital tools [10, 11].

Objectives

The aim of this study was to examine the recruitment process within the ENERGISED randomised controlled trial. The specific objectives were to:

1. Describe the recruitment flow, including patient characteristics at each stage and reasons for ineligibility (potential selection bias) and non-consent (potential self-selection bias);
2. Investigate selection and self-selection bias at the GP and patient level, respectively; and
3. Investigate the relationship between GP characteristics, eligibility rates, and potential selection bias.

Methods

This study was conducted within the ENERGISED randomised controlled trial (ClinicalTrials.gov identifier NCT05351359; registered 28 April 2022), a 12-month pragmatic, multicentre trial evaluating a digitally supported physical activity intervention for adults with prediabetes or uncomplicated type 2 diabetes recruited through Czech general practices. The protocol was approved by the Ethics Committee of the General University Hospital in Prague (reference number: 49/20). Full details of the trial design, procedures, and statistical analysis plan have been published elsewhere [12,13]. Between April 2022 and April 2024, 343 patients were recruited through 28 participating GP practices. The present paper focuses exclusively on the recruitment process, including patient flow, eligibility assessments, and consent.

Recruitment of general practices

General practices were recruited through national GP conferences, a professional journal, direct e-mail invitations, and personal contacts, as described previously [12]. The original protocol envisaged participation of 21 practices, but this was later expanded to 28 to accelerate recruitment and ensure broader representation. The participating practices included 15 from urban areas and 13 from rural towns with fewer than 30,000 inhabitants, covering 9 of the 14 administrative regions of the Czech Republic. Participating GPs received remote training on study procedures and data entry and were compensated for their time (approximately €100 per patient completing the study).

Patient eligibility

Eligibility criteria were identical to those specified in the published ENERGISED protocol [12]. Patients were eligible if they met all of the following: (1) diagnosis of prediabetes or type 2 diabetes according to Czech guidelines for GPs (fasting plasma glucose 5.6–6.9

mmol/l or 2-h plasma glucose of 7.8–11.0 mmol/l after ingestion of 75 g of oral glucose load for the diagnosis of prediabetes fasting plasma glucose ≥ 7.0 mmol/l or 2-h plasma glucose ≥ 11.1 mmol/l after ingestion of 75 g of the oral glucose load for the diagnosis of type 2 diabetes); (2) age ≥18 years; (3) followed for prediabetes or diabetes by a participating GP (in the Czech Republic, GPs typically manage patients with uncomplicated type 2 diabetes with glycated haemoglobin (HbA1c) ≤ 53 mmol/mol who are not treated with insulin); (4) regular users of a mobile phone (not necessarily a smartphone), able and willing to answer calls and read text messages as part of the study; (5) able and willing to wear and use a wrist-worn Fitbit activity tracker for the study duration; and (6) provided written informed consent. As the Fitbit required a smartphone for initialisation, patients without their own smartphones were advised to ask a relative or friend to perform the setup.

Exclusion criteria were: (1) unable to walk independently for any reason; (2) pregnant; (3) having a household member already recruited for thw trial; (4) living in a residential or nursing care home where the imposed regime could interfere with the intervention; or (5) having co-morbid conditions that would seriously affect adherence, including active malignancy; recent (< 3 months) myocardial infarction, coronary artery bypass graft or cerebrovascular accident; renal disease requiring dialysis; neurological condition (e.g., Parkinson disease); cognitive impairment, or significant hearing or visual impairment; hip or knee joint replacement within three months; or major surgery planned within the next 12 months. Because all study materials and procedures were in Czech, patients were excluded if they lacked sufficient Czech language proficiency to participate effectively.

Recruitment process

Before recruitment began, each GP generated a registry-based list of all patients with prediabetes or type 2 diabetes in their practice. From this list, practices received an initial stratified random batch of 24 patients (sex 1:1, condition prediabetes:diabetes 1:2). GPs were required to assess eligibility of all sampled patients opportunistically during routine health check-ups conducted every 3 to 6 months.

During routine visits, GPs first assessed eligibility based on predefined criteria using medical records and a brief discussion with the patient. Eligibility was determined using routine clinical judgement rather than a structured assessment of patients' own willingness or perceived capability. Eligible patients were then informed about the study during the same visit, provided with written study information, and invited to participate. Patients were given the opportunity to ask questions and to decide whether to provide written informed consent either at the same visit or at a subsequent visit, according to their preference.

GPs documented reasons for ineligibility and non-consent using predefined categories in the electronic case report form, with an option to add brief free-text clarification when needed. When an initial batch was exhausted, additional random batches of 12 patients were issued as needed until the practice depleted its original list, reached 32 recruited patients, or the overall trial target was met (planned 340; actually 343 recruited).

Patients who consented underwent baseline procedures, including seven days of wrist-worn accelerometry, followed by a second baseline visit where participants received a Fitbit activity tracker. After the second baseline visit, patients were randomly allocated in a 1:1 ratio to either the intervention or the active control arm.

Recruitment stages

Importantly, the study design required GPs to assess all patients from randomly selected lists, thereby minimising discretionary inclusion and reducing selection bias at the assessment stage. Recruitment losses were systematically tracked and categorised as either GP-determined ineligibility or patient-declared non-consent, allowing detailed insight into the factors contributing to recruitment attrition in a primary care trial.

For the purpose of this study, we use the following terms to describe the successive recruitment stages: (1) total population, (2) sampled, (3) assessed, (4) eligible, (5) consented, and (6) randomised patients.

The *total population* includes all patients with prediabetes or type 2 diabetes registered at participating GP practices. A list of these patients was generated by the GPs using computerised medical records before recruitment began.

Sampled patients are those randomly selected from the total population, stratified by sex (female: male in a 1:1 ratio) and condition (prediabetes: diabetes in a 1:2 ratio). Each practice initially received a batch of 24 sampled patients. When this batch was exhausted, new random selections of 12 patients were generated and provided as needed.

Assessed patients are those among the sampled patients who were assessed for eligibility by their GP. As recruitment was conducted opportunistically during routine health check-ups, patients who did not attend their scheduled visits during the recruitment period could not be assessed.

Eligible patients are those assessed and confirmed to meet all eligibility criteria.

Consented patients are eligible individuals who provided written informed consent to participate in the trial.

Randomised patients are those who consented and were subsequently randomised. As the protocol involved an interval of at least one week between consent and randomisation, not all consenting patients were randomised.

This study focuses exclusively on the recruitment process up to the point of randomisation. However, as both GPs' and patients' motivations may have been shaped by their expectations regarding the potential benefits and burdens of the trial procedures, a brief overview of the intervention and control conditions, as well as the trial visits and outcomes, is provided here.

Intervention and control conditions

Both trial arms involved a wrist-worn activity tracker and brief physical activity advice delivered by GPs during baseline visits. Participants were encouraged to monitor daily step counts and gradually increase physical activity. Patients allocated to the intervention group additionally received a digital mobile health (mHealth) intervention consisting of automated text messages, complemented by telephone counselling during the first six months, whereas the active control group received no digital or counselling components beyond the activity tracker and brief advice. Full details of the intervention content and delivery are provided in the published protocol and intervention development papers [12,14].

Trial visits and outcomes

Trial procedures included two baseline visits followed by follow-up visits at 3, 6, and 12 months. In routine Czech primary care, patients with type 2 diabetes typically attend quarterly visits and those with prediabetes biannual visits; participation therefore required only one additional visit for patients with diabetes and two for those with prediabetes. Outcome measures and assessment procedures are described in detail in the published protocol and statistical analysis plan [12,13].

Statistical analysis

Descriptive statistics were used to summarise the characteristics of participating GPs and patients at each stage of the recruitment process. Continuous variables are reported as medians with interquartile ranges (IQR) or means with standard deviations (SD), and categorical variables as counts and percentages. There were no missing data for patient characteristics, recruitment outcomes, or GP-level variables.

To examine potential selection and self-selection bias, logistic mixed-effects models were used, with GP included as a random intercept to account for clustering at the practice level. Four binary outcomes were modelled: (1) consented vs. not consented among all sampled patients; (2) assessed vs. not assessed among sampled patients; (3) eligible vs. not eligible among those assessed; and (4) consented vs. not consented among those eligible. The four binary outcomes were chosen to reflect distinct stages of the recruitment pathway, allowing separation of potential sources of bias at different points in the process: opportunity for eligibility assessment (assessed vs. not assessed), GP eligibility assessment (eligible vs. not eligible), and patient decision-making (consented vs. not consented). Although non-assessment was largely driven by non-attendance at scheduled visits, this stage was analysed separately to examine whether patient characteristics were associated with differential opportunity to be assessed.

Each model included patient-level predictors: sex, age (calculated at the start of recruitment) and clinical condition (diabetes or prediabetes). Age was included as a continuous linear term; non-linear specifications were not explored. In cases where a significant patient-level predictor of eligibility or consent was identified, we further explored its relationship with specific reported reasons for ineligibility or non-consent. For each reason, a separate logistic regression model was fitted, with the presence or absence of that reason as the binary outcome and the significant patient-level predictor as the independent variable. These models were restricted to the relevant subsample (ineligible or non-consenting patients). Odds ratios (ORs) with 95 % confidence intervals (CI) and *p*-values were reported.

To examine whether general practitioners' characteristics are associated with eligibility rates and potential selection bias, a logistic mixed-effects model was constructed among assessed patients, with eligibility (yes/no) as the outcome and GP included as a random effect. GP-level predictors included sex, years since graduation, practice type (solitary vs. associated), practice location (urban vs. non-urban), number of registered patients, and the proportions of registered patients with diabetes or prediabetes, aged over 65 years, and the proportion of those who had undergone a preventive examination in the past two years. Model selection followed a stepwise approach. Starting from a full model including all patient-level and GP-level variables, non-significant fixed effects were removed sequentially, beginning with the predictor with the highest *p*-value. After obtaining a reduced model, two-way interaction terms between selected patient-level and GP-level variables were added to explore potential moderating effects.

All trial data were collected using REDCap electronic data capture tools. Statistical analyses were conducted in R (version 4.4.2) using the lme4 package.

Results

Characteristics of participating GPs

The trial involved 28 GPs from 28 practices, of whom 24 were women. The median number of years since graduation was 17 (IQR: 12 to 24). Thirteen GPs were based in cities with over 100,000 inhabitants, while 15 practised in smaller towns or rural areas. Twenty-one worked in solitary practices, and 7 in group or associated practices.

The median number of registered patients per GP was 1,818 (IQR: 1,584 to 2,048). The mean proportion of patients registered for regular follow-up with diabetes or prediabetes was 4.5 % (SD: 3.9). The mean proportion of patients aged over 65 years was 24.6% (SD: 6.9). In 2021, the mean proportion of patients who underwent a preventive health check was 25.7% (SD: 10.8). As preventive health checks are scheduled biennially, some patients may have attended in 2020 or subsequently in 2022, and the overall coverage is therefore higher than reflected in the 2021 data.

Recruitment flow and patient characteristics

Among all 3,579 patients with diabetes or prediabetes registered with the 28 participating GPs, a stratified random sample of 1,376 patients was selected. Of these, 1,138 (82.7%) were assessed for eligibility by their GPs, and 792 (69.6% of those assessed) were deemed eligible. Among the eligible patients, 348 (43.9%) consented to participate, and 343 (43.3%) were ultimately randomised, with 5 patients not showing up for the second baseline visit. The recruitment flow is summarised in Figure 1.

Table 1 presents the characteristics of patients at each stage of the recruitment process: the total population, sampled patients, those assessed for eligibility, those deemed eligible, and those who consented. Figure 2 shows the number of patients assessed, found eligible, and consented per individual GP.

Selection and self-selection bias at the patient level

To assess potential selection and self-selection bias, we first compared patients who consented to participate with those in the randomly sampled population. Increasing age was associated with lower odds of progressing through the stages of assessment, eligibility, and consent (OR = 0.965 per year, 95% CI: 0.954–0.976, $p < 0.001$). In contrast, there were no significant differences in sex or clinical condition between consenting and sampled patients. We then examined each stage of the recruitment process separately. No significant differences were found between assessed and sampled patients, suggesting no bias in the assessment stage. However, both the eligibility stage (selection bias) and the consent stage (self-selection bias) showed the same age-related pattern: older patients were less likely to be deemed eligible (OR = 0.955 per year, 95% CI: 0.942–0.968, $p < 0.001$) and less likely to consent (OR = 0.972 per year, 95% CI: 0.958–0.986, $p < 0.001$). Again, no significant differences were observed for sex or clinical condition at these stages.

Reasons for ineligibility and non-consent

The reasons for ineligibility are summarised in Table 2. The most common reasons for ineligibility were an anticipated inability to use the wrist-worn Fitbit activity tracker throughout the study period (n = 126) and not being a regular user of a mobile phone or being unable to read text messages (n = 101). The age-related bias observed in the overall eligibility analysis was consistent across most specific reasons for ineligibility, with the only common reason not related to increasing age being registration with a diabetologist (Table 2).

The reasons for non-consent are summarised in Table 3. Among patients who were eligible but did not consent, the most frequently cited reasons were a lack of interest in a physical activity intervention (n = 172) and insufficient time (n = 158). The odds of non-consent due to lack of interest increased with age (OR = 1.02, 95% CI: 1.002–1.041, $p = 0.03$), whereas the odds of non-consent due to lack of time decreased with age (OR = 0.971, 95% CI: 0.954–0.99, $p = 0.002$).

Influence of GP characteristics on eligibility rates and selection bias

We next examined whether GP-level characteristics were associated with eligibility rates and whether they moderated potential selection bias. Based on the final model, patients assessed by female GPs had higher odds of being deemed eligible (OR = 5.38, 95% CI: 1.97–14.67, $p = 0.001$). Similarly, GPs with a higher proportion of registered patients with diabetes or prediabetes had greater eligibility rates (OR = 1.15 per percentage point, 95% CI: 1.04–1.28, $p = 0.008$).

Moreover, GPs with a larger proportion of registered patients aged over 65 years exhibited a stronger age-related bias during the eligibility stage, as indicated by a significant interaction between patient age (per year) and the proportion of older registered patients (per percentage point) (interaction OR = 0.996, 95% CI: 0.995–0.998, $p < 0.001$). This interaction means that the negative effect of age on eligibility is stronger in GP practices with more older patients. In contrast, in practices with fewer older patients, the difference in eligibility between younger and older patients is smaller.

No other GP-level characteristics were significantly associated with eligibility rates or with the strength of the age-related bias.

Discussion

Summary of main findings

Increasing age was strongly associated with both ineligibility (selection bias) and non-consent (self-selection bias). Among patients assessed as ineligible, 36% were unable to use a Fitbit device and 29% did not use a mobile phone, two inclusion criteria that disproportionately affected older individuals. Other exclusion reasons included comorbidities, limited mobility, and institutionalisation. These findings underscore how apparently neutral criteria, especially those involving technology, can systematically exclude older or more vulnerable patients and limit trial generalisability [1,15,16].

In terms of self-selection, older patients most often declined participation due to lack of interest, while younger patients more frequently cited lack of time. This divergence reflects previously reported generational differences in motivation and perceived relevance of digital or behavioural health interventions [2,3]. Interestingly, no significant differences were observed by sex or by clinical condition (diabetes versus prediabetes), suggesting that these factors had little influence on patient engagement in this context.

At the practice level, patients assessed by female GPs and by those in practices with a higher proportion of diabetes or prediabetes patients had significantly higher eligibility rates—findings aligned with existing evidence linking GP characteristics to recruitment patterns [17]. Furthermore, the age-related decline in eligibility was most pronounced in practices with a higher proportion of older registered patients. This suggests that selection bias may be compounded in settings where both patient and practice characteristics contribute to disengagement or perceived unsuitability [11, 18].

Taken together, these results show that even with structured recruitment protocols and digital tools, trials in general practice remain susceptible to systematic exclusions—particularly of older adults—unless such barriers are explicitly anticipated and addressed during trial design.

Comparison with existing literature

While the association between older age and reduced participation in digital health interventions is well established, our study demonstrates this effect quantitatively and clearly within a trial recruitment process. Age-related barriers, particularly the inability to use a Fitbit device or mobile phone, were among the leading reasons for ineligibility. This strengthens previous observations regarding the digital divide and trial participation among older populations [1,15,16]. While some technology-related exclusion reasons reflect objective barriers, such as not owning or using a mobile phone, others may represent preferences or perceived difficulties rather than absolute inability, and could potentially be mitigated through additional support or alternative technological solutions.

In addition to digital or physical limitations, older adults may decline participation due to a combination of psychological and perceptual factors. These include fatigue, fear of being overwhelmed by procedures, mistrust or confusion about research aims, and concerns about loss of autonomy or perceived burden [19, 20]. Prior studies have shown that older individuals often underestimate the relevance or benefit of participation or may feel that younger populations are more appropriate candidates for health interventions [21,22,23].

A key contribution of this study is the clear separation of GP-determined ineligibility from patient-declared non-consent. Eligibility was influenced not only by patient characteristics, but also by GP and practice-level factors. Higher eligibility rates were observed among patients assessed by female GPs and in practices with a higher proportion of patients with diabetes or prediabetes. These associations should be interpreted with caution, particularly those related to GPgender, given the small number of male GPs in the sample. Nevertheless, they are broadly consistent with previous research suggesting that gender-based communication styles and contextual familiarity with the condition may influence how clinicians interpret eligibility criteria and engage with patients [17].

Among patients who were eligible but declined participation, age-related differences in motivation were apparent. Older patients were more likely to report a lack of interest, while younger individuals more frequently cited time constraints, highlighting distinct generational patterns in perceived relevance and capacity to engage in behavioural research [2, 3].

Furthermore, the interaction between patient age and the age distribution of the GP's practice revealed that age-related bias was amplified in practices with an older registered population. This finding suggests that recruitment bias may be systematically reinforced at the practice level, a nuance rarely captured in previous studies. From a general practice perspective, this may reflect the practical workload constraints in surgeries with a high proportion of older, often chronically ill patients. These practices may experience greater time pressure and complexity in consultations, reducing capacity to engage in extended recruitment conversations [11, 18]. As a result, GPs might, consciously or unconsciously, be more likely to exclude older patients, especially those perceived as less likely to benefit or more difficult to engage.

Strengths and limitations

A major strength of this study is its comprehensive and pragmatic recruitment framework. We applied a stratified random sampling approach to minimise clinician-driven selection and used mixed-effects modelling to distinguish patient-level from GP-level influences on recruitment outcomes. In addition, we collected structured, standardised data on reasons for both ineligibility and non-consent, allowing for a nuanced understanding of the specific mechanisms underlying recruitment attrition.

Moreover, our conversion rate from invitation to randomisation notably surpasses earlier primary care walking trials such as PACE-Lift [24] and PACE-UP [25]. PACE-UP, which relied on postal invitations, achieved a recruitment rate of about 10%, while reported positive response rates for similar interventions, including PACE-Lift, ranged from 6% to 35%. In contrast, our face-to-face recruitment approach resulted in substantially higher participant engagement and uptake, underscoring both the feasibility and advantage of personalised, in-person strategies in general practice settings.

However, several limitations should be acknowledged. First, our findings arise from recruitment into a digitally supported behavioural intervention requiring use of wearable devices and mobile communication; therefore, the observed patterns of selection and self-selection bias may not fully generalise to trials without digital components. Second, although reasons for non-consent were self-reported and eligibility assessments followed predefined criteria, some technically framed reasons for ineligibility, such as anticipated inability or unwillingness to use a Fitbit device, may have reflected subjective preferences or assumptions rather than true objective barriers. This raises the possibility of a mismatch between GP and patient judgement, whereby some patients classified as ineligible, particularly for technology-related reasons, might nevertheless have been willing to attempt participation. Moreover, the face-to-face nature of recruitment may have allowed subtle influences of GP perceptions, for example regarding digital literacy or capacity to engage, to shape how the study was presented and how the patients responded. These interactional aspects could not be examined within the current study and warrant further qualitative investigation. Third, although GP characteristics were included in the models, the GP sample was highly imbalanced, with only four male participants. Any associations involving GP gender should therefore be interpreted with particular caution, as the study was not adequately powered to assess gender-specific effects or interactions at the GP level. Fourth, key sociodemographic and cognitive factors, such as educational attainment, employment status, digital literacy, or socioeconomic status, were not captured, which may confound or mediate some observed associations. In particular, differences in employment or retirement status may have contributed to the observed age-related differences in reported time constraints. Finally, patient-reported reasons for non-consent may have been influenced by social desirability, with stated lack of interest potentially masking concerns about confidence or perceived ability to engage with the intervention.

Implications for research and practice

These findings have practical implications for trials of digitally supported behavioural interventions in general practice. For future studies, targeted recruitment support, such as simplified procedures or additional guidance, may be particularly beneficial for practices with differential or low eligibility rates, as observed in this study among practices with a higher proportion of older adults or fewer patients with diabetes or prediabetes. Such approaches may help reduce selection bias, improve representativeness, and increase recruitment efficiency in digitally supported trials. However, it should be noted that participating practices were recruited through professional networks and conferences and received financial compensation, which likely selected more research-active or motivated general practices. As such, the feasibility and effectiveness of similar recruitment strategies may differ in less research-engaged practices.

The growing prevalence of diabetes and prediabetes, conditions frequently described as part of a global metabolic epidemic, further highlights the urgency of developing effective and scalable prevention strategies. General practitioners, who serve as the primary contact point for patients with or at risk of chronic conditions, are ideally positioned to support such interventions. Our findings offer insight into real-world recruitment dynamics that are likely to be relevant not only in the Czech context but also in other healthcare systems with ageing populations and increasing metabolic burden.

Lastly, while our findings are likely to be representative of Czech primary care, differences in healthcare structure, digital access, and patient–GP relationships in other countries may limit broader applicability. Nevertheless, the challenges we identified, particularly those related to age, digital engagement, and recruitment dynamics, are likely relevant to many health systems. The systematic integration of GPs in the recruitment process provides a pragmatic and potentially replicable model for trial implementation internationally.

Importantly, general practice in the Czech Republic differs from that in the UK and other countries. Most Czech practices are single-handed, with one GP responsible for all patient care, rather than team-based or group practices. Furthermore, patients with type 2 diabetes and prediabetes are typically managed directly by GPs, with minimal involvement of practice nurses or other allied professionals. These structural differences may influence recruitment feasibility and clinician–patient interactions, and should be considered when interpreting the transferability of our findings to other healthcare systems.

Conclusions

This study demonstrates that a systematic, GP-integrated recruitment strategy can meaningfully reduce selection bias and self-selection bias, improve standardisation across sites and achieve a high recruitment rate in a trial of a digitally supported behavioural intervention. However, even with this design, GP-level selection bias and patient-level self-selection bias, particularly those associated with age, persisted. Digital limitations were a major driver of ineligibility, while motivational misalignments, especially among older adults, contributed to lower consent. The ability to distinguish GP versus patient-level contributions enabled a more nuanced understanding of recruitment barriers in primary care trials.

Although conducted in a single national context, the challenges identified, such as digital exclusion, age-related barriers, and motivational mismatches, are broadly applicable across primary care systems facing similar epidemiological and technological transitions. As the burden of type 2 diabetes and prediabetes continues to rise globally, the need for inclusive and scalable trial designs becomes increasingly urgent. Greater attention to recruitment equity and digital accessibility is essential to ensure that digital health research in general practice reflects the diversity of real-world patient populations.

List of abbreviations

CI: confidence interval; GP: general practitioner; IQR: interquartile range; JITAI: just-in-time adaptive intervention; OR: odds ratio; SD: standard deviation

Declarations

Ethics approval and consent to participate

The study protocol has been approved by the Ethics Committee of the General University Hospital, Prague (No. 49/20), and the study was conducted in compliance with the principles of the Declaration of Helsinki. Informed consent to participate in the study was obtained from participants.

Consent for publication

Not applicable.

Availability of data and material

The datasets generated during the current study are available from the corresponding author upon reasonable request.

Competing interests

The authors declare no competing interests.

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Authors' contributions

Conceptualisation: NK, BS, MP, TV, TH, TY, MU, IM, DVD, SE, JP, MS, KJ, CW, PD. Data curation: NK, VC, KM, JK, TV, PD. Formal analysis: VC, TV, NK. Funding acquisition: TV, RC, BS. Investigation: MP, NK, KM, JK. Methodology: BS, NK, MP, VC, JK, AR, SE, DVD, IM, TH, JD, TY, TV, MU. Project administration: MS, BS, RC, KM, TV. Resources: TV, JN, JK, MP, NK, JD, KM, RC, BS, JD. Software: JK, RC. Supervision: BS, TH, TY, AR, TV, MU, JP, SE, DVD. Writing - original draft: NK, TH, TV. Writing - review & editing: all authors.

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Figures

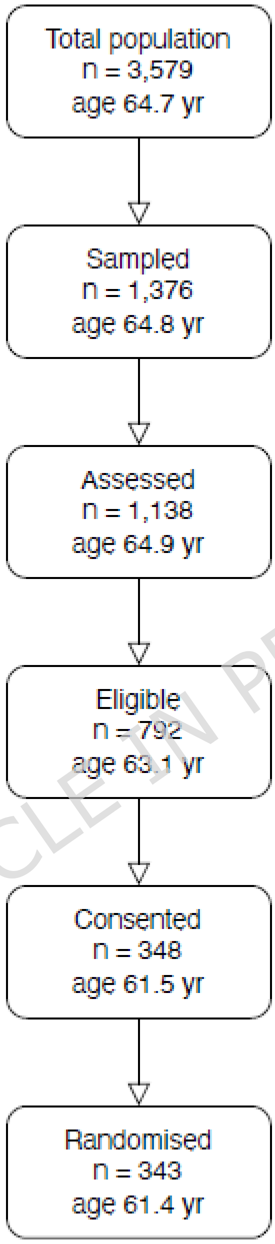

Figure 1. Recruitment flowchart with the number of individuals and their mean age at each stage

Figure 2. Number of patients assessed, eligible, and consenting per individual general practitioner

Note: Horizontal lines indicate the mean number of patients assessed, eligible, and consented.

Tables

Table 1. Characteristics of patients at each stage of the recruitment process: total population, sampled, assessed, eligible, and consenting patients

Stage	**Sex**	**Condition**	**Count (n, %)**	**Age (mean ± SD)**
Total Population	Male	Diabetes	950 (26.5%)	65.5 ± 11.4
		Prediabetes	978 (27.3%)	60.0 ± 13.2
	Female	Diabetes	803 (22.4%)	70.1 ± 11.7
		Prediabetes	848 (23.7%)	64.3 ± 13.6
Sampled	Male	Diabetes	478 (34.7%)	64.1 ± 11.0
		Prediabetes	237 (17.2%)	59.2 ± 12.3
	Female	Diabetes	442 (32.1%)	68.7 ± 11.2
		Prediabetes	219 (15.9%)	64.4 ± 13.6
Assessed	Male	Diabetes	393 (34.5%)	64.2 ± 11.0
		Prediabetes	190 (16.7%)	59.1 ± 12.6
	Female	Diabetes	379 (33.3%)	68.5 ± 11.4
		Prediabetes	176 (15.5%)	65.0 ± 13.8
Eligible	Male	Diabetes	272 (34.3%)	63.0 ± 10.4
		Prediabetes	145 (18.3%)	57.0 ± 12.1
	Female	Diabetes	256 (32.3%)	66.7 ± 11.2
		Prediabetes	119 (15.0%)	63.0 ± 12.7
Consented	Male	Diabetes	127 (36.5%)	62.7 ± 10.7
		Prediabetes	62 (17.8%)	54.6 ± 12.1
	Female	Diabetes	109 (31.3%)	64.4 ± 10.7
		Prediabetes	50 (14.4%)	60.6 ± 11.7

Table 2. Reported reasons for ineligibility and their association with patient age

Reason for non-eligibility	Count	OR	95% CI	p-value
Unable to use Fitbit*	126	1.11	1.08–1.14	0.0000
Not using a phone**	101	1.12	1.08–1.16	0.0000
Registered with a diabetologist	60	1.00	0.97–1.02	0.7436
Comorbidities	52	1.05	1.02–1.09	0.0006
Not registered with the practitioner	50	1.05	1.02–1.08	0.0018
Unable to walk	40	1.14	1.09–1.19	0.0000
Institutionalised	16	1.06	1.00–1.12	0.0510
On insulin	13	1.01	0.95–1.08	0.6890
Not having pre/diabetes	12	0.97	0.93–1.01	0.1655
Household member already enrolled	10	1.06	0.99–1.14	0.0878
Not speaking Czech	9	0.97	0.91–1.04	0.3995

* 'Unable to use Fitbit' refers to patients who reported being unable to initialise or use the device.
** 'Not using a phone' refers to patients who reported no regular use of a mobile phone.

Table 3. Reported reasons for non-consent and their association with patient age

Reason for non-consent	Count	OR	95% CI	p-value
Lack of interest	172	1.02	1.00–1.04	0.0303
Lack of time	158	0.97	0.95–0.99	0.0023
Not willing to use Fitbit	83	1.00	0.98–1.03	0.8404
Other	77	1.03	1.00–1.05	0.0324
Not willing to receive calls	51	1.00	0.97–1.03	0.8968
Privacy reasons	48	1.00	0.97–1.03	0.9205
Not willing to get messages	46	1.02	0.99–1.06	0.1517
Already wearing a tracker	24	0.96	0.93–0.99	0.0175