

Evaluation of intervention fidelity and moderating factors in a multicentre randomised controlled trial

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Abstract

Background

In multicentre trials of complex interventions, several factors can moderate the effects of an intervention. This creates the possibility of a type III error if the intervention is evaluated under conditions that do not adequately reflect its intended delivery, rendering conclusions about effectiveness difficult to interpret. A prerequisite for interpreting trial outcomes is therefore to assess whether the intervention was implemented as intended. To this end, our study aims to perform a post-hoc fidelity assessment of NSAC Efficacy, a multicentre randomised controlled trial implemented in five outpatient clinics across Northern Norway to evaluate the efficacy of a work-focused, multidisciplinary intervention on work -and health outcomes.

Methods

The fidelity assessment was based on a modified conceptual framework of implementation fidelity, evaluating adherence to content, coverage and timeliness and seven potential moderators. We employed a sequential mixed-methods design, analysing quantitative and qualitative data collected concurrently and retrospectively during the trial.

Results

Intervention personnel adhered to content, coverage and timeliness by delivering work-focused, multidisciplinary services within set timelines to patients at risk of or on sickness absence due to musculoskeletal issues and/or common mental health disorders. Several strategies were employed prior to and during the trial to facilitate implementation, ensure quality of delivery and maintain engagement with intervention personnel. The study protocol and policy descriptions were clear and concise regarding what was to be delivered in the intervention. Recruitment challenges were observed, with a reduction in referrals over time. Similarly, there were changes in organisation and personnel over time, as well as differences between clinics in practice and organisation, which may have functioned as contextual moderators.

Conclusions

Our results indicate that the intervention was implemented as intended. The available data did not suggest that any moderator systematically undermined intervention fidelity, supporting the interpretability of forthcoming outcome analyses from NSAC Efficacy. Because the fidelity protocol was not pre-specified, and the assessment relies primarily on self-report from intervention personnel, sensitivity to subtle threats to fidelity is limited.

Trial registration:

The trial was prospectively registered at clinicaltrials.gov on March 3rd, 2022. Trial identifier: NCT05310695.

Background

A three-arm multicentre randomised controlled trial (RCT; NSAC Efficacy) was implemented in five existing Health In Work clinics (Helse I Arbeid; hereafter referred to as HIA) in Northern Norway between January 2023 and October 2025 to determine the effect of an outpatient work-focused intervention on work participation and health [1]. RCTs are the most rigorous way to evaluate efficacy of an intervention since the design minimises the influence of potential confounding variables [2, 3]. The defining trait of the RCT-design, internal validity, rests on an assumption which is rarely made explicit; that the intervention is delivered as intended. In multicentre trials of complex interventions, where several active components must be implemented across multiple clinics, this assumption can be easily violated, constituting a threat to both internal validity and the attribution of observed effects to the intervention. Several possible factors could moderate the effects of an intervention on its outcomes. One such factor is fidelity [4, 5].

The terminology and definition of fidelity is inconsistent in the research literature but is usually defined as *“the extent to which an intervention/programme is implemented/delivered as intended/planned”* [6]. Fidelity is one of the key elements of process evaluations [7, 8] and is essential for understanding how and why an intervention works, and how contextual factors may affect outcomes [5, 9, 10]. This evaluation is particularly important for multicentre trials, given the possibility of the intervention being implemented and received differently [2].

Despite the importance of fidelity assessment, Toomey and colleagues [6] posit in their scoping review that it remains poorly addressed in existing research and highlight several potential implications for the interpretation of intervention outcomes. In addition to type I and type II errors concerning statistical properties of hypothesis testing, (i.e., rejecting the null hypothesis when it is true and failing to reject the null hypothesis when it is false [11]) a distinct threat arises when the intervention which is tested has not been adequately implemented. This reflects a type III error, in which both null and positive findings become uninterpretable, since they cannot be attributed to the intervention [12]. Thus, to determine the efficacy of an intervention, it is necessary to first establish whether it was implemented as intended (5, 9).

Aim

The aim of the present study is to evaluate the extent to which the NSAC Efficacy trial was implemented as intended across clinics in a multicentre RCT. As the trial was implemented in existing outpatient clinics, fidelity will be evaluated by examining adherence to I) the HIA-service as outlined in policy descriptions, and II) the interventions delivered to the different randomisation groups as outlined in the study protocol. The core components of the HIA-service are mirrored in the core components of the intervention-arm of the RCT. For this reason, fidelity assessment of the HIA-service and fidelity assessment of the intervention of the RCT are the same.

Our research questions are:

1. Was the HIA-service delivered in accordance with policy descriptions?
2. Was the intervention delivered in accordance with the study protocol?
3. How did potential moderating factors influence overall intervention fidelity?

Methods

Study design

The post-hoc fidelity assessment employed a sequential mixed-methods design. Quantitative process data were collected longitudinally and concurrently with RCT enrolment and outcome data collection. To minimise the risk of contaminating RCT outcomes, qualitative data were collected through focus groups interviews after the final RCT data points were collected. Additionally, administrative data and policy descriptions were reviewed to evaluate the degree to which intervention delivery corresponded to the intended service model of HIA. Several strategies to facilitate implementation of the RCT were planned and undertaken before and during the trial (Additional file 1). Although implementation was identified at trial registration as one of the planned work packages of the broader NSAC project, specific fidelity procedures, instruments and outcomes were not pre-specified.

To properly assess the fidelity of our intervention, we have adhered to the recommendations posed by Toomey and colleagues [8] to address overarching fidelity issues (i.e., clearly define fidelity, make use of an existing framework, report use of strategies to enhance fidelity, and assess fidelity beyond intervention delivery).

Study setting

The NSAC Efficacy study was conducted in five pre-existing HIA outpatient clinics organised in the specialist healthcare sector in Northern Norway. The clinics are located in Kirkenes (Finnmark Hospital), Tromsø and Harstad (University Hospital of Northern Norway), Bodø (Nordland Hospital) and Sandnessjøen (Helgeland Hospital), and serve a larger catchment area in their vicinity, constituting a population of approximately 500.000 people.

Description of the HIA-service

The HIA-service is intended to deliver rapid, simultaneous, coordinated, co-located, work-focused evaluation and/or treatment from a multidisciplinary team to people at risk of or on sickness absence (SA) due to musculoskeletal disorders (MSDs) and/or common mental health disorders (CMDs; primarily anxiety and depression [13]). The goal of the service is to increase/improve work participation and provide healthcare. The basic staff model of the multidisciplinary team consists of physicians specialising in physical medicine and rehabilitation (hereby referred to simply as physicians), physiotherapists, psychologists and employment support supervisors from the Norwegian Labour and Welfare Administration (Nav; hereby referred to as HIA-counsellors). Patients are primarily referred to HIA from their general practitioner (GP). Since HIA in Northern Norway is administratively located within the Physical Medicine and Rehabilitation clinic (FMR), referrals from GPs are first sorted between clinics before a team of clinicians at HIA evaluate eligibility for the HIA-service. Eligibility for admission is based on national guidelines for diagnosis and symptom severity and inclusion- and exclusion-criteria for the HIA-service [1, 14], and whether patients are considered to fit within intended target group as outlined above. The admission team at HIA usually consists of one or more physicians, a psychologist and in some clinics also a physiotherapist.

The HIA-service emerged from a national policy process aimed at consolidating and institutionalising work-focused health service within the specialist healthcare sector. Their immediate precursor was Raskere Tilbake (Rapid Return to Work), a government-funded initiative operative from 2007 to 2017, which provided rapid-access outpatient services to individuals on or at risk of SA. When this programme was discontinued, its work-focused services were integrated into ordinary specialist healthcare provision under the designation HelselArbeid, from 2018 onwards. The conceptual framework for this transition was set out in a joint policy report from the Norwegian Directorate of Health (Hdir) and Nav, recommending a national two-component model comprising an individual clinical service and a workplace service [13]. A subsequent longitudinal follow-up evaluation commissioned by the four regional health authorities documented the consequences of this transition at system, service, and patient level, and noted

considerable variation in service delivery and nomenclature across clinics nationally, as well as challenges in demonstrating effects on SA in registry data [15]. HIA thus represents a nationally mandated but locally implemented specialist service, a characteristic that is directly relevant to the assessment of implementation fidelity in the present study.

Description of the RCT

The NSAC Efficacy study was a multicentre RCT implemented in five HIA outpatient clinics with the aim of determining the effect of HIA on work participation and health. The trial had an a priori target of 2500 patients, where patients were randomised in equal proportions to either of three groups:

1. HIA-rapid (delivered within 4 weeks). This group received the usual HIA-service offered at the clinics within 4 weeks, a time point considered ideal according to policy descriptions for the HIA-service.
2. Delayed HIA (delivered between 10–14 weeks). This group received the same service as group A, but at a later time point.
3. Active control (delivered between 8–26 weeks, usually close to 26 weeks). This group received a monodisciplinary evaluation over 1–2 sessions, typically from a physiotherapist or psychologist. The evaluation was meant to resemble an evaluation the patient could expect to receive in other health services, entailing a focus on health rather than work. The same intervention personnel (IP) delivered services to both the control group and the intervention groups. The IP performing the evaluation was allowed to consult a physician on matters considered acute or beyond the scope of their professional competencies.

Recruitment was initiated January 16th, 2023, and was completed October 15th, 2025. A detailed account of the intervention, including inclusion -and exclusion criteria, is available in the study protocol [1] and trial registration (NCT05310695). The description provided in the present study is limited to information relevant to the fidelity assessment of the trial.

Recruitment

Patients considered eligible for HIA were contacted by a research coordinator (RC) at each clinic per telephone to retrieve patient information and to give patients information about the study. Upon acceptance, patient details (i.e., email, personal identifier, deadline for assessment as determined by national guidelines, and recommended profession to perform assessment if randomised to group C) were entered in an online custom-built interface linked to a digital survey tool (Tivian A/S, Oslo Norway). Patients were blindly randomised by the survey tool. Patients that did not consent to participate received the same assessment as the active control group (i.e., a monodisciplinary assessment). Not responding to the consent form within 14 days was treated as a non-consent [1].

Upon randomisation, patients received a baseline digital questionnaire through the digital interface. In addition to demographic questions, the questionnaire covered health-related issues (musculoskeletal, mental health, sleep, alcohol consumption and medication), work and work-related factors (such as social support, bullying, perceived barriers for return to work and work motivation) and expectations for treatment at HIA. The questionnaire provided to the active control group was less comprehensive than the questionnaire provided to the intervention groups. A complete overview of the questionnaire batteries and other included variables can be found in supplemental appendices in Aars et al., 2026 [1]. Psychometrically evaluated index questions were used to reduce number of questions posed to each patient.

A conceptual framework for fidelity assessment

There are numerous conceptual frameworks for fidelity with different terminology and definitions [6]. Implementation fidelity and intervention fidelity are the most prevalent terms, sometimes used interchangeably within the same study [6]. Authors have, however, argued the need for differentiating between them. Based on the integrative definitions posed by Demers and colleagues [4], we have in this article assessed intervention fidelity, defined as «*the degree to which the intervention is implemented as intended; the correspondence between the intended intervention and the actual implementation of the intervention*». We have based our fidelity assessment on the modified conceptual framework for implementation fidelity posed by Hasson [16], based on the original framework developed by Carroll and colleagues [5]. Although both frameworks use the term implementation fidelity, they are argued to have a strong focus on intervention fidelity [17]. The different dimensions and moderators of fidelity are argued to both influence each other and the outcomes [4, 5, 16, 18].

According to this framework, fidelity is assessed through adherence to 1) content, 2) coverage, 3) frequency and 4) duration. Content refers to whether the core components of the intervention were delivered to recipients [5, 16]. Coverage, also referred to as the intervention's reach, reflects whether all participants eligible for the intervention were included, and if participants randomised to the intervention arm of the study received the intervention [5, 16]. Frequency and duration, more broadly defined as "dose" or "dosage", pertain to whether components of the intervention were implemented as often and long as intended [5, 16].

There were no regulations in the study protocol regarding how frequently or long IP were supposed to deliver the intervention. Conversely, one of the core components of the intervention was to ensure a short time from referral to first consultation (timeliness of initiation). To fit the fidelity assessment to our study, we therefore chose to remove frequency and duration as measurements of adherence and add timeliness (Fig. 1). Timeliness refers to whether the intervention was delivered at the right time [4, 19] and has been included in modified versions of the original conceptual framework of Carroll and colleagues [5, 18, 19].

The framework presents seven potential moderators in total: four originating from the conceptual framework of Carroll et al. [5], two added by Hasson [16], and one incorporated by Carroll in a later update [18]. Participant responsiveness assesses engagement and satisfaction of those delivering and receiving the intervention [5, 16]. Comprehensiveness of policy description, also called intervention complexity, refers to how specific the description of the intervention is [16]. Specific, detailed and simple interventions are more likely to be implemented with high fidelity compared to those that are vague and/or complex [5]. Strategies to facilitate implementation may include provision of manuals, guidelines, training, monitoring and feedback to participants delivering the intervention [5]. Quality of delivery addresses how well participants delivered the intervention [18], i.e., whether the intervention was delivered in a way that was appropriate to achieving what was intended [5]. The two moderators added by Hasson [16], recruitment and context, refer to consistency of recruitment procedures, subgroups less likely to participate and reasons for nonparticipation among potential participants [20] and whether factors at the political, economic, organisational and workgroup levels affected the implementation [16]. Context includes anything external to the intervention that may act as a barrier or facilitator to its implementation, or its effects [7].

Based on his analysis of 20 studies, Carroll [18] recommended time to be included as a moderator in any new framework and integrated it in an updated version of his original conceptual framework from 2007. The argument, supported by empirical evidence, is that adherence and moderators of fidelity might increase or decrease over time, such as participant responsiveness, potentially impacting intervention outcomes [18]. Given that NSAC Efficacy was implemented for 2.5 years, it is plausible to assume that intervention fidelity might be affected over time, necessitating its assessment.

Figure 1. Modified conceptual framework for intervention fidelity

The modified framework is based on the conceptual framework for implementation fidelity first proposed by Carroll and colleagues [5] and later modified by Hasson [16] and Carroll [18].

Data sources

To assess the adherence-components and potential moderating factors, we employed a mixed-methods approach using data gathered concurrently and retrospectively during the trial. For an overview of the different data sources and the fidelity components they were used to assess, see Additional file 2.

Quantitative data

The quantitative data sources consisted of self-report surveys from IP after first consultation, baseline self-reports from patients, data reported by RCs, accumulated consent during recruitment period and percentage of consent per month, as well as descriptive data on attrition rate and randomisation amongst patients consenting to the study.

As part of the RCT data collection, all IP were asked to fill out a clinician survey after each consultation. The survey intended to capture the duration and main topics of the consultation, procedures and/or interventions delivered, as well as professions included during the consultation. A complete list of questions included in the IP survey is available in the appendices in Aars et al. [1]. The information from the surveys included in the data analyses were limited to the first consultation of each patient, where we looked at the date of the consultation, whether other professions were involved and degree of work focus. Degree of work focus was assessed by counting the number of work-related variables reported to be addressed in the consultation. In total, the survey consisted of 37 work-related items. Data reported from the RCs regarding deadline for first consultation of each patient was compared to the date of the first consultation as reported by the IP to assess whether the consultation occurred within the specified deadline.

From the patient baseline survey, we extracted information about their work status, musculoskeletal issues and mental health issues. For work status, patients marked all variables relevant to describe their work situation, for instance “work, fulltime”, “self-employed” and “graded sick leave”. For musculoskeletal issues, patients responded to the question “*Do you have musculoskeletal problems that restrict you in work, leisure or affect your sleep?*” on a 5-point Likert scale (1 = not at all, 5 = yes, to a large extent). Mental health issues were assessed through Hopkins Symptoms Checklist – 10 (HSCL-10). A score at 1.85 or higher was estimated to represent case level symptoms of anxiety and depression [21].

Accumulated consent during recruitment period and percentage of consent per month was used to evaluate whether there were changes in recruitment and consent during the study period. These data were retrospectively retrieved from Tivian (the digital interface) after recruitment was completed. Additionally, patient attrition rate was used to assess participant responsiveness.

Qualitative data

The qualitative process data consisted of focus group interviews and one individual interview with a sample of IP from the HIA outpatient clinics, as well as the study protocol and project management documentation (Additional

file 2).

The interviews were conducted between September 16th and November 5th, 2025. Two members of the research team moderated the interviews, using a semi-structured interview guide (Additional file 3). The purpose was to get an in-depth description of the context of each HIA-clinic and how they operated locally, as well as the IPs' experiences with implementing the intervention during the RCT.

A total of twenty IP participated, including three physicians, five physiotherapists, four psychologists, one social worker with further education in psychotherapy, two managers, two HIA-counsellors, one hospital secretary, one employment consultant and one quality advisor. The interviews consisted of four to six IP each and had an average duration of 68 minutes (min. 30 min, max. 1 h and 38 min).

The study protocol was used to assess whether core components of the trial were adhered to. Project management documentation was used to illustrate what strategies were used to facilitate implementation fidelity and the time of their implementation (Additional file 1).

Policy descriptions and guidelines

In addition to quantitative and qualitative data sources, we used policy descriptions, guidelines and other related documents to evaluate the fidelity of the HIA-service (such as the concept description of HIA [13] and a report from a national inter-regional workgroup regarding work-focused treatment in the specialist healthcare sector [22]).

Data analyses

Quantitative data

The different quantitative data sources were linked using the patients unique 11-digit personal identifier entered in the system by the RC. We used descriptive statistics to calculate the number of days from recruitment to first assessment (mean and standard deviation). The proportion (percentage and number of participants) of patients with musculoskeletal complaints or symptoms of anxiety/depression was calculated using complete case analyses, excluding patients with missing data on the variables in question. For work status, the categories were not mutually exclusive, and the number of statuses therefore exceed 2500.

Qualitative data

The interviews with IP were analysed with a deductive thematic content analysis. The audio recordings were transcribed verbatim and coded manually according to the adherence categories and potential moderators from our chosen conceptual framework for assessing intervention fidelity. The researcher performing the interviews, coding and analyses was independent of and unaffiliated with the trial site and the clinical team.

Results

The presentation of results is structured according to our modified conceptual framework for intervention fidelity, first assessing adherence to content, coverage and timeliness, and then potential moderators.

Adherence to content

Adherence to content was assessed through evaluation of level of multidisciplinary and work-focus for the intervention groups and the control group. As presented in Tables 1 and 2, patients in the intervention groups received a multidisciplinary service, whereas the control group received a monodisciplinary assessment, adhering to both the policy descriptions of the HIA-service and the study protocol. The slightly elevated score for physiotherapist-assessment for group C was due to involvement of physicians in consultations where it was deemed necessary to ensure proper medical assessment of the patient, in line with the protocol.

Adherence to delivery of a multidisciplinary and work-focused service was further corroborated by IP reports in the focus group interviews. IP stated that it was difficult to refrain from addressing work with control group patients, as they considered work-focus an essential part of HIA and felt it was ingrained in their clinical practice. Work-focus as measured by IPs’ reports after the first consultation was, however, more prevalent in the intervention groups than the control group.

Table 1
The average number of professions involved in the first consultation

IP profession	Psychologist			Physiotherapist		
Randomisation group	A	B	C	A	B	C
Number of professions involved. Mean (SD)	2.0 (1.0)	1.8 (0.9)	1.0 (0.1)	2.3 (1.1)	2.4 (1.0)	1.2 (0.4)

The table presents the average number of professions involved in the first consultation, as reported in IP surveys. The trial was designed in such a way that most patients enrolled to the trial either had their first consultation with a physiotherapist or a psychologist. For this reason, the table separates between IP surveys filled out by these two professions. Similarly, to evaluate the level of multidisciplinary services, we separated data for the respective randomisation arms (group A, B and C).

Table 2
The average count of work variables addressed in the first consultation

Randomisation group	Number of work variables addressed in the first consultation (M, SD)
A	7.3 (5.0)
B	7.2 (4.8)
C	5.0 (4.2)

Data from the IP survey filled out by IP after the first consultation with a patient. The survey has 37 work variables in total.

Adherence to coverage

The descriptive data (Table 3) show that 70.8% of patients scored above 1.85 on HSCL-10 (M = 2.29), representing case level symptoms of anxiety and depression. Furthermore, 71% of patients reported having musculoskeletal problems that restricted them in work, leisure or affected their sleep to some or to a large extent. Regarding work status, 60% of patients reported being on graded or full SA, 47% reported working full time, and only a small percentage (10%) reported having applied for- or currently receiving work assessment allowance or disability

pension. Coverage of target group was further corroborated by information from focus group interviews, both regarding health conditions and work status. According to IP, comorbid physical and psychological issues or disorders were typical for patients referred to HIA.

Table 3
Descriptive data on gender, work status, mental health issues and musculoskeletal issues

Descriptive data	Frequency (%)	Missing response
Gender		
Woman	1757 (70.1%)	
Man	750 (29.9%)	
Work status		69 (2.8%)
Work full-time	1143 (45.6%)	
Work part-time	267 (10.7%)	
Self-employed	115 (4.6%)	
Student	84 (3.4%)	
Graded sick leave	602 (24%)	
Full sick leave	874 (34.9%)	
Unemployed	62 (2.5%)	
Applied for work assessment allowance	104 (4.1%)	
Receiving work assessment allowance	152 (6.1%)	
Have applied for disability benefits	7 (0.3%)	
Maternity leave	6 (0.2%)	
Receives cash support	3 (0.1%)	
Neither salary nor any form of social security	11 (0.4%)	
Other, describe	190 (7.6%)	
HSCL-10 mean score		141 (5.6%)
HSCL-10 mean score < 1.85	589 (23.5%)	
HSCL-10 mean score > = 1.85	1777 (70.9%)	
Do you have musculoskeletal problems that restrict you in work, leisure or affect your sleep?		26 (1.0%)
Not at all	190 (7.6%)	
No, to a small extent	222 (8.9%)	
A little	290 (11.6%)	
Yes, to some extent	737 (29.4%)	
Yes, to a large extent	1042 (41.6%)	
The categories for current work status were not mutually exclusive, as patients could report several categories as relevant descriptions of their current work status. For HSCL-10, a score at 1.85 or higher is estimated to represent case level symptoms of anxiety and depression.		

Table 3. Descriptive data on gender, work status, mental health issues and musculoskeletal issues

The categories for current work status were not mutually exclusive, as patients could report several categories as relevant descriptions of their current work status. For HSCL-10, a score at 1.85 or higher is estimated to represent case level symptoms of anxiety and depression.

Adherence to timeliness

Combined data reported by RCs (deadline for first consultation) and IP (date of first consultation) indicate that the intervention was delivered at the pre-specified timeframe across all randomisation groups (Table 4). The average number of days from referral to first visit (expected vs. actual) show a discrepancy of only 3 days for consultations with a psychologist. First visit with a physiotherapist was delivered within deadline as registered by the RC for all randomisation groups but was delivered earlier for groups B and C (16 days earlier for group B and 23 days earlier for group C, on average). It was reported from IP in the focus group interviews that all clinics except one managed to stay well within the deadlines. Deviations from deadline occurred during holidays, resulting in patients randomised to group A (consultation within 4 weeks of referral) receiving first consultation after 5–6 weeks. Despite intermittent challenges with availability of necessary IP, it was stated in focus group interviews by IP that they mostly managed to deliver the intervention on time.

Table 4
Expected versus actual time from referral to first consultation

IP profession	Psychologist			Physiotherapist		
	A (n = 363)	B (n = 432)	C (n = 380)	A (n = 437)	B (n = 458)	C (n = 430)
Randomisation group						
Expected: days from referral to first consultation. Mean (SD)	28 (7)	70 (14)	70 (14)	28 (7)	84 (7)	150 (21)
Actual: days from referral to first consultation. Mean (SD)	31 (30)	68 (35)	67 (20)	28 (22)	68 (32)	127 (47)

Most of the patients enrolled to the trial either had their first consultation with a physiotherapist or a psychologist. For this reason, the table separates between IP surveys filled out by these two professions. Given that the different randomisation groups (A, B, C) had different deadlines for the first consultation, as specified in the study protocol, the table separates data for the respective randomisation groups.

Potential moderating factors

Participant responsiveness

In focus group interviews IP reported frustration and emotional strain due to limited ability to advise the active control group and non-consenting participants, as it conflicted with their professional desire to help and what they considered beneficial to the patient. It was reported from IP that they felt the control group received a lesser service than the intervention groups, especially pertaining to lack of work-focus, multidisciplinary access and waiting time. Interview data indicated that patients often had limited understanding of both the consequences of declining participation and the implications of being randomised to the control group. According to IP, this led patients to expect the same service as those allocated to the intervention arm, which in turn contributed to a perceived sense among IP of having let these patients down. This was especially the case for patients with mental health conditions.

Conversely, IP described working with patients in the intervention group as rewarding, as it enabled delivery of the intervention in line with the usual HIA-practice.

Regarding patient responsiveness, patients were mostly described by IP in focus group interviews to be highly motivated. IP reported generally receiving positive feedback from patients, expressing appreciation for the multidisciplinary service. This responsiveness is reflected in the low trial attrition rate (Fig. 2). Of all 2500 patients enrolled to the trial, only 15 withdrew their consent: 3 from group B and 12 from group C.

Figure 2: Flowchart inclusion and attrition

Comprehensiveness of policy description

The policy description of HIA [13] and the study protocol [1] presented clear directions regarding both delivery and organisation of the HIA-service and the trial. Beyond adherence to timeliness (time from referral to first consultation), content (work focus and multidisciplinary components), and coverage (patients at risk of or on sick leave due to MSDs and/or CMDs), both the HIA service and the trial allowed flexibility in intervention delivery, reflecting its pragmatic implementation within existing outpatient clinics across multiple sites. Thus, context-specific or time-dependent adaptations were allowed, granted that content, coverage and timeliness were adhered to. Although the RCT and intervention could be described as complex, we evaluated policy descriptions to be clear and concise.

Strategies to facilitate implementation

Strategies to facilitate implementation were somewhat described in policy descriptions and were prospectively planned and conducted continuously from before initiation of the RCT until its completion, as informed by the project management documentation (Additional file 1). Strategies included revision of trial design in collaboration with participating clinics prior to recruitment, development of protocol for control group with IP, revision of questionnaire and software based on IP feedback, monthly meetings with clinic management, seminars for participant clinics, training of RCs (digitally and in seminars), bi-weekly meetings with RCs, project management visits to participating clinics, annual regional HIA-conferences with IP, collaborators and researchers involved in the trial, sending information letters to all GPs in coverage area to inform about the trial, as well as intermittent visits from a group of IP in each clinic to surrounding GP offices to inform about the HIA-service and the ongoing RCT. Several strategies entailed close collaboration with and feedback from clinicians and leadership, especially from the largest clinics (Tromsø and Bodø) prior to and during initiation of the trial to facilitate implementation. In addition, IP reported in focus group interviews that they employed several strategies targeting both new and experienced staff to ensure that service delivery adhered to policy descriptions and the study protocol. These strategies are further outlined in assessment of quality of delivery.

Quality of delivery

In addition to adherence to the intervention, strategies were implemented throughout the trial to ensure consistency across sites and to build the necessary competencies among IP (e.g., annual regional HIA conferences, seminars with participating clinics and IP, and digital and in-person training of RCs; Additional file 1). Focus group interviews indicated that additional training and routines were implemented across clinics to ensure high-quality delivery in accordance with guidelines and the protocol. For instance, new employees were provided training to ensure shared understanding of the core components of the HIA-service as well as consistency in intervention delivery throughout the study. The training consisted of regular professional training related to procedures and routines relevant to the

respective professions, introduction to the service and the multidisciplinary nature of HIA, multidisciplinary job shadowing, and information about the ongoing trial and protocol. IP reported that the clinics practiced regular multidisciplinary meetings, giving opportunities for clarification of what IP could and could not deliver to patients. In one clinic it was stated by IP participating in the interviews that physicians employed on short-term contracts did not receive full training due to limited time. This was also reported to be the case for short-term psychologist services. In these cases, IP considered work-focus to be potentially compromised. To address this, more experienced IP often provided additional assistance and guidance to improve quality of delivery.

Recruitment

The proportion of patients consenting to the trial remained stable throughout the recruitment period (Fig. 3). However, the absolute number of patients referred to HIA declined over time. These reductions happened despite efforts from IP in the different clinics to improve recruitment rates and ensuring that eligible patients were referred to HIA (Additional file 1). Focus group interviews showed that all clinics followed similar procedures for assessing patient eligibility for inclusion in HIA: a physician performed the referral assessment, often together with a physiotherapist and/or a psychologist. Referral assessment procedures were thus comparable across HIA-clinics. However, since referrals from GPs are received and evaluated jointly in two clinics (i.e., HIA and FMR; described in the methods-section), referrals that did not request a specific service were assessed for eligibility based on referral information and allocation to the service considered most appropriate for the patient. Given the possibility that patients might have received a limited service and experienced long waiting times at HIA, IP reported in focus group interviews being more reluctant than before the trial to refer patients to HIA, even when they considered them suitable. Furthermore, several IP reported in the focus group interviews that fatigue and greater symptom load were reasons for both active- and passive non-participation.

Figure 3: Consent during recruitment period

Context

Information from focus group interviews with IP indicated overall commonality between the five HIA-clinics in organisation and staffing. All clinics were organised under the hospital unit FMR and had a basic staff model consisting of one or more physicians, physiotherapists, psychologists and HIA-counsellors. Presence of HIA-counsellors varied between clinics, from 2 to 5 weekdays. Some locations had additional resources, such as social workers and/or nurses with psychotherapeutic education and an occupational therapist. Furthermore, all clinics had regular multidisciplinary meetings to discuss patients. Based on IP reports in focus group interviews, the average number of sessions for the intervention groups was relatively similar across clinics. However, IP stated great variability in content and length of the service offered to each patient, dependent on the patient's specific issues, progression during treatment and what the clinic had to offer.

Patients enrolled in the trial were not restricted from seeking services elsewhere. Based on information from focus group interviews with IP, all but one location was reported to have similar number (6–7) of services in their geographical area of coverage relevant to the target population of HIA. One location (Kirkenes, Finnmark Hospital) only had 2–3 such services. Furthermore, two services with the greatest overlap with HIA in terms of target population and service provision—Senter for Jobbmestring (At Work and Coping; AWaC) and Rask Psykisk Helsehjelp (RPH)—were limited across catchment areas, particularly in those served by Finnmark Hospital. The University Hospital of Northern Norway (Tromsø) was the only location with both services available, while areas covered by Nordland hospital (Bodø) and Helgeland hospital (Sandnessjøen) only had a few municipalities within their catchment area that offered RPH. Neither of these overlapping services existed in areas covered by Finnmark

hospital. Available services similar to HIA listed by IP in focus group interviews were primarily services offered by municipalities, rendering patients access to such services dependent upon their place of residence. IP interviewed in all clinics reported limited access and long waiting times for the services offered in their catchment area. Focus group interviews with IP indicated that patients randomised to the control group were more often referred to other services, such as rehabilitation, as IP were unable to provide the multidisciplinary service they considered necessary at HIA. They did, however, underscore the difficulty of getting patients into such services due to limited availability, especially in the smaller or more remote municipalities.

Time

While consent remained stable throughout the trial period, recruitment declined (Fig. 3). In focus group interviews, IP reported dissatisfaction among GPs regarding the long waiting times for non-consenting patients or patients randomised to the active control group. They suggested that this may have been influenced by a bias in feedback from patients, in that patients having to wait longer for their first consultation were more likely to complain about it to their GP than patients receiving an assessment within four weeks.

In focus group interviews, IP reported variations over time in contextual factors (i.e., turnover and access to necessary professions) in the different HIA-clinics. During the trial period, two clinics experienced minimal to no staff turnover, and no absence of specific professions. The other three clinics reported high turnover, periods with limited access to physicians and psychologists, and difficulties in staff recruitment. Furthermore, two clinics reported temporary absence of a RC tasked to perform recruitment of patients. Despite these challenges, IP emphasized that they managed to deliver the intervention in accordance with the study protocol and policy descriptions. For instance, they reported that other IP took on recruitment responsibilities of the RC in addition to their regular workload, to ensure eligible patients were enrolled to the trial.

Discussion

This study has evaluated the intervention fidelity of NSAC Efficacy, a multicentre RCT implemented across five HIA outpatient clinics. The clinics offer quick, work-focused, multidisciplinary services to patient at risk of or on sick leave due to MSDs and/or CMDs, with the aim of improving work participation and health. Using an established framework for evaluation of implementation fidelity and a mixed-methods approach, the results show that the intervention was implemented as intended, adhering to content, coverage and timeliness. Although there were no indications of any moderators systematically undermining the fidelity of the intervention, several factors may nevertheless have influenced its implementation in positive and negative ways.

Adherence to content, coverage and timeliness

Fidelity was assessed through adherence to content, coverage and timeliness. With respect to content, the core components of the intervention were delivered as intended, in accordance with the study protocol and policy descriptions. The intervention groups received work-focused and multidisciplinary services, while the control group received a monodisciplinary assessment with limited work-focus. Although reports from IP questionnaires showed a higher work-focus in the intervention groups, it remains uncertain to what extent the level of work-focus in the control group reflects routine clinical practice outside the trial. IP stated in focus group interviews that it felt unnatural and difficult to refrain from addressing patient's work situation. One reason for this, suggested to explain the null-finding in the Nudge trial [23], conducted within the same study setting and with the same population, is that work-focus was an automated and intrinsic part of IPs practice in HIA-clinics. If the trial setting itself introduced a

heightened awareness of occupational function in the control condition, this could represent a form of contamination that attenuates the true contrast between conditions. Such a threat to internal validity warrants consideration when interpreting between-group differences in the trial.

A lack of equipoise amongst IP represents a plausible alternative explanation for the level of work-focus in the control condition. When clinicians deliver an intervention within an RCT, conflicts may arise between their roles as clinicians and researchers, particularly when the allocated treatment does not align with their views on best clinical practice [24]. Such a lack of equipoise can affect delivery [24], despite clinician's intentions to set aside personal biases [25]. Although not a direct test of this hypothesis, IP reports from the focus group interviews are consistent with such a notion. IP described feeling unable to provide non-consenting patients and those in the control group with what they considered "appropriate" care, and being constrained in sharing information they deemed beneficial. Despite this internal conflict, IP stated in interviews that they chose to adhere to the protocol. Strategies to facilitate implementation fidelity and ensure quality of delivery, such as annual HIA-conferences and weekly multidisciplinary meetings, likely fostered adherence amongst IP. Nevertheless, a standard health-focused clinical assessment would be expected to address occupational functioning as part of routine case formulation, given that work status and educational background are standard components of psychiatric and psychological evaluations.

Regarding timeliness, results show that time of delivery was adhered to for both intervention groups and the control group. Although most patients in group B and C received their first consultation earlier than the set deadline (Table 4), the study protocol required assessment of patients to be given within deadline, not on deadline. This reflects a flexibility in delivery format that maintains fidelity while also preserving the clinical responsiveness of IP. Flexibility is not considered to affect fidelity if the core components of the intervention are implemented as intended, reflective of the recommended balance between fixed and flexible elements in intervention delivery [5, 8]. Adherence to timeliness support the internal validity of the study, as deviations in timing responses represents a well-documented threat to treatment fidelity [26].

Potential moderators

Overall, neither of the moderators appear to have systematically undermined the intervention fidelity. Findings do, however, suggest that several contextual and implementation-related factors may have shaped intervention implementation in both constraining and facilitating ways. Several strategies were employed prior to and during the trial to facilitate implementation and ensure competency amongst IP delivering the intervention, likely bolstering quality of delivery and participant responsiveness. These strategies also entailed close collaboration with clinicians and leaders in the different clinics, inviting them to contribute to joint decisions regarding trial design and implementation conditions. This approach aimed to foster a sense of ownership among IP personnel, which may have supported sustained engagement with the intervention throughout the trial. Indeed, statements from focus group interviews indicate high engagement and motivation amongst both IP and patients, especially for the intervention-arms of the trial. We evaluated the policy descriptions and study protocol to be clear and concise, balancing fidelity with the need for flexibility in intervention delivery and improving the likelihood of the intervention being implemented with high fidelity [5, 8]. Recruitment and context could, however, potentially have undermined the intervention fidelity, in part as a function of time.

Recruitment

Despite achieving target sample size and having a low attrition rate, results showed a decline in recruitment over the course of the recruitment period. Such a dip in recruitment rate within the first year has also been reported by others

[27]. Recruitment issues are commonly reported in RCTs, and several trials need an extended recruitment period to reach the recruitment target [28–31]. In a comprehensive review by Jacques and colleagues [28], median consent rate in 388 RCTs was 72%, indicating that the average consent rate of 74.3% in our trial is satisfactory.

Given that patient consent remained stable throughout the recruitment period (Fig. 3), a plausible explanation for the reduced recruitment is a reduced rate of patient referrals from GPs. Focus group data suggested that GPs expressed dissatisfaction with the randomisation of the trial leading to long waiting times and limited services. A possible reinforcing mechanism is that the GPs may have received selective feedback from patients allocated to the control condition. Consequently, over time GPs may then have formed a belief that referring patients to the HIA-service was not worthwhile, presumably resulting in decreased referrals over time. A reduced willingness by GPs to refer patients to HIA could affect recruitment and coverage if not all eligible patients were reached. The gatekeeping function of GPs in clinical research has been reported in the literature [32], wherein a clear factor in reducing GPs' willingness to refer patients to trials was the risk of patients not receiving the intervention because of randomisation [33, 34]. This sentiment amongst GPs seems to also have been the case for IP evaluating eligibility of patients referred from GP. In interviews they reported being more reticent in advocating for inclusion in the HIA-service due to risk of the patient being randomised to the control group, reflecting a lack of equipoise [24]. However, as referral motivations were not systematically assessed, this interpretation remains inferential and cannot be tested directly with the present data.

Another aspect of the recruitment process that might have affected the trial's reach, is the risk of recruitment bias in favour of more functional and less symptomatic patients. Patients were considered eligible for HIA before they were asked to participate in the trial. However, patients actively or passively not consenting to participate typically had more fatigue according to IP in focus group interviews. Although symptom load has been reported as a reason for nonparticipation in other studies [35, 36], several other reasons for nonparticipation have been stated that are not due to severity of health complaints, such as length of time required to read trial material and a lack of understanding of the trial [34, 37]. According to IP reports, patients had expectations of receiving the same service regardless of participation or non-participation.

Context

Contextual factors were broadly comparable across clinics with respect to organisation, referral assessment and staffing, supporting the assumption of implementation heterogeneity across clinics. However, several clinics experienced transient periods with limited access to specific professions, such as physicians, psychologists and RCs. Reported efforts to mitigate this were, amongst others, redistribution of work tasks and employing necessary professions on short-term contracts. Additionally, although IP from different clinics reported an overlap in estimated average number of sessions per patient, they highlighted great variability in course of treatment, dependent on patient-factors and what the specific HIA-clinic had to offer. These variations in staffing and treatment across clinics did not appear to systematically undermine fidelity. Such uncontrolled contextual variability could, however, have introduced heterogeneity in intervention delivery that has not been fully captured by the present fidelity measures – a limitation of particular relevance in multisite trials where implementation conditions are rarely uniform.

Patients enrolled in the trial were not restricted from seeking services elsewhere, and IP reported more often referring control group patients to other services than intervention group patients. This creates the possibility of patients receiving multiple services, making it more difficult to distinguish effects of the intervention alone. The likelihood of patients seeking other services depends on availability of services in their vicinity. Patients residing in the municipalities Tromsø and Bodø have access to more private and public health services similar to HIA than

patients residing in more rural areas, such as those covered by Sandnessjøen and Kirkenes. This is in accordance with the internationally reported rural-urban divide in availability of healthcare services [38, 39, 40]. The likelihood of patients utilising other services than HIA is especially high for patients with musculoskeletal issues, given the longer deadline for assessment, as outlined in national guidelines [14]. Thus, differences in availability of other healthcare services could moderate the results of NSAC Efficacy, particularly for patients in the control group.

Strengths and limitations

A methodological strength of this study is that our fidelity assessment is based on a clear definition of fidelity and a standardised framework, assessing a breadth of fidelity-components which extended beyond delivery of the intervention. Critically, the NSAC Efficacy protocol incorporated explicit flexibility provisions, allowing clinics and IPs to adapt delivery procedures, provided that core intervention components were maintained and delivered to the intended target population within pre-specified timeframes. This design reflects a deliberate balance between fidelity and adaptation – a balance increasingly recognised as essential in pragmatic multisite trials implemented in clinical settings, where rigid adherence to protocol may itself constitute a threat to external validity [17]. Several strategies were employed to facilitate implementation of the trial from before its initiation until its completion. This negates most of the overarching methodological intervention fidelity issues described by Toomey and colleagues [8]. The use of mixed methods and several data sources facilitated a comprehensive evaluation of fidelity, where the quantitative data and qualitative data were found to be both aligned and complementary. This allowed us to not only measure statistical trends but also provided context as to why these results could have occurred through the IPs own experiences.

A particular strength of our approach is that fidelity was assessed for both the intervention and the control group, a feature highlighted as important in previous research [41, 42]. Adherence to protocol for the control group could be an even more important measure of fidelity in our trial, given that the same IP delivered services to the intervention groups and the control group. This is considered a limitation of the trial design, as it creates the possibility of lack of equipoise and the risk of spillover or contamination in the services delivered by IP. A primary limitation is the post-hoc nature of the fidelity assessment. As a prospective fidelity protocol was not pre-specified, the available data were not systematically designed to operationalise all fidelity components, and the sensitivity of the measures to detect deviations from intended delivery cannot be fully established. Furthermore, there are some limitations in the data sources used to assess fidelity. Patient data was limited to a baseline questionnaire, limiting the ability to assess patient engagement and adherence, and controlling potential other health services delivered to the patient. Patient outcomes are not only dependent upon how the intervention was delivered by IP, but also whether patients adhered to action plans agreed upon with their IP, such as exercises, exposure practices and other types of homework. It is, however, not considered feasible to obtain such data in a study setting such as ours.

Conclusions

The available evidence did not reveal systematic deviations from the intended delivery of the NSAC Efficacy intervention. Adherence to content, coverage and timeliness was supported across both quantitative and qualitative data sources, in line with the study protocol and policy descriptions. None of the potential moderators we examined appeared to undermine fidelity in a way that would systematically compromise interpretation of the trial's main outcomes, although recruitment declined over time and contextual variation between clinics is likely to have introduced some heterogeneity in delivery that the present measures cannot fully capture. The strategies used to facilitate implementation were extensive and likely contributed to the consistency we observed. Such strategies appear particularly important in non-blinded trials where the same personnel deliver intervention and control

conditions. Defining which core components of the intervention must be adhered to, while allowing for contextually appropriate adaptations, may enhance both the feasibility and the external validity of the intervention. Evaluating the fidelity of a trial using a clear conceptual understanding of fidelity and a standardised framework is an important prerequisite for proper interpretation of the outcomes of the NSAC Efficacy study. Our results indicate that the intervention was implemented as intended, and that potential moderators are unlikely to have had a substantial impact on trial outcomes. Thus, our assessment supports the position that the forthcoming outcome analyses from NSAC Efficacy can be interpreted as reflecting the intervention as designed, with a correspondingly reduced, though not eliminated, risk of a type III error.

Abbreviations

HIA

Health in Work

MSD

Musculoskeletal disorder

CMD

Common mental health disorder

GP

General Practitioner

FMR

Physical Medicine and Rehabilitation clinic

SA

Sickness Absence

Nav

Norwegian Labour and Welfare Administration

Hdir

Norwegian Directorate of Health

RC

Research coordinator

IP

Intervention personnel

HSCL-10

Hopkins Symptoms Checklist-10

AWaC

At Work and Coping

RPH

Rask Psykisk Helsehjelp (Improving Access to Psychological Therapies)

Declarations

Ethics approval and consent to participate

This study was approved by the Regional Committee for Medical and Health Research Ethics (REC North), approval no. #122770, and conducted in accordance with the Declaration of Helsinki. All participants who contributed data provided informed consent.

Consent for publication

Not applicable.

Availability of data and materials

The datasets analysed during the current study are not publicly available due to ethical and privacy restrictions. The findings are available within the article. Otherwise, the datasets are available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

The study was conceived by AM, BB and NAA. MM wrote the first draft of the manuscript, which was critically revised by all co-authors at several stages. KSS participated in the collection, transcription, analyses and writing of the qualitative data reported in the manuscript. AI contributed to description of study setting, interpretation of results and in the discussion of the findings. All authors have read and approved the final manuscript.

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Authors' information

MM and AI worked as psychologists in one of the clinics where the trial was implemented. This dual role provides insights that are different from the researchers and project coordinators and that are of great relevance when evaluating how the intervention was implemented.

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Figures

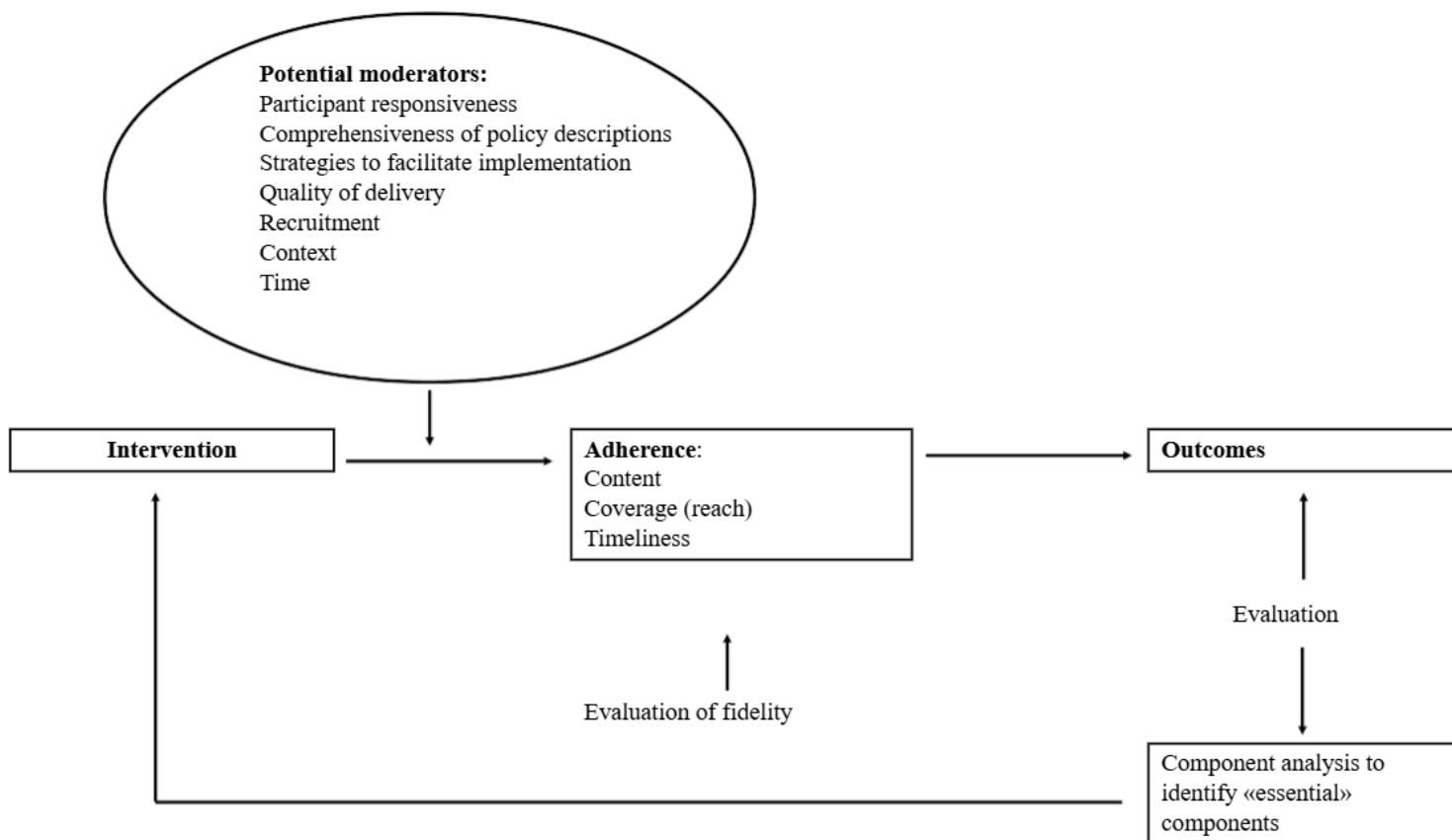


Figure 1

Modified conceptual framework for intervention fidelity

Enrolment

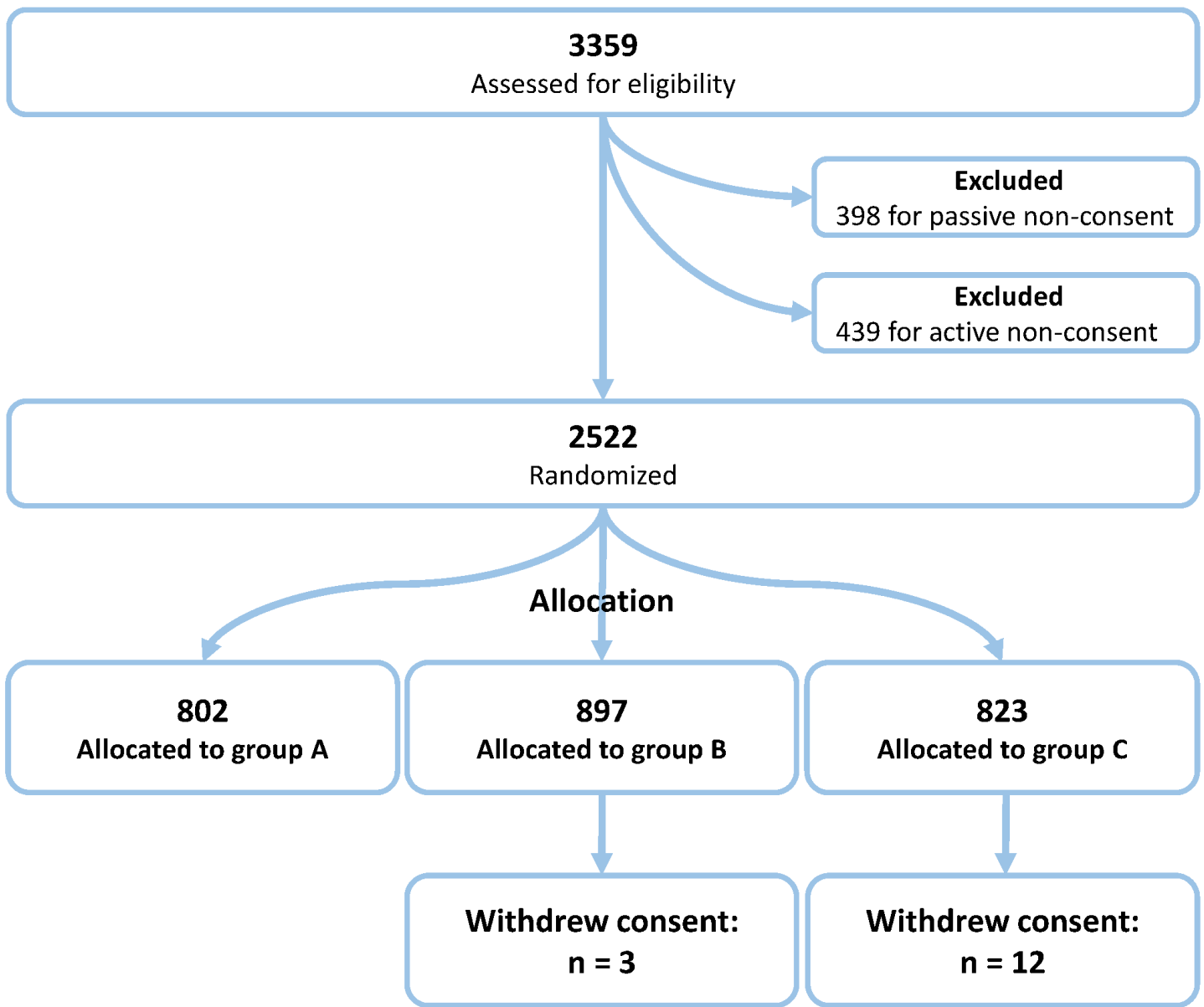


Figure 2

Flowchart inclusion and attrition

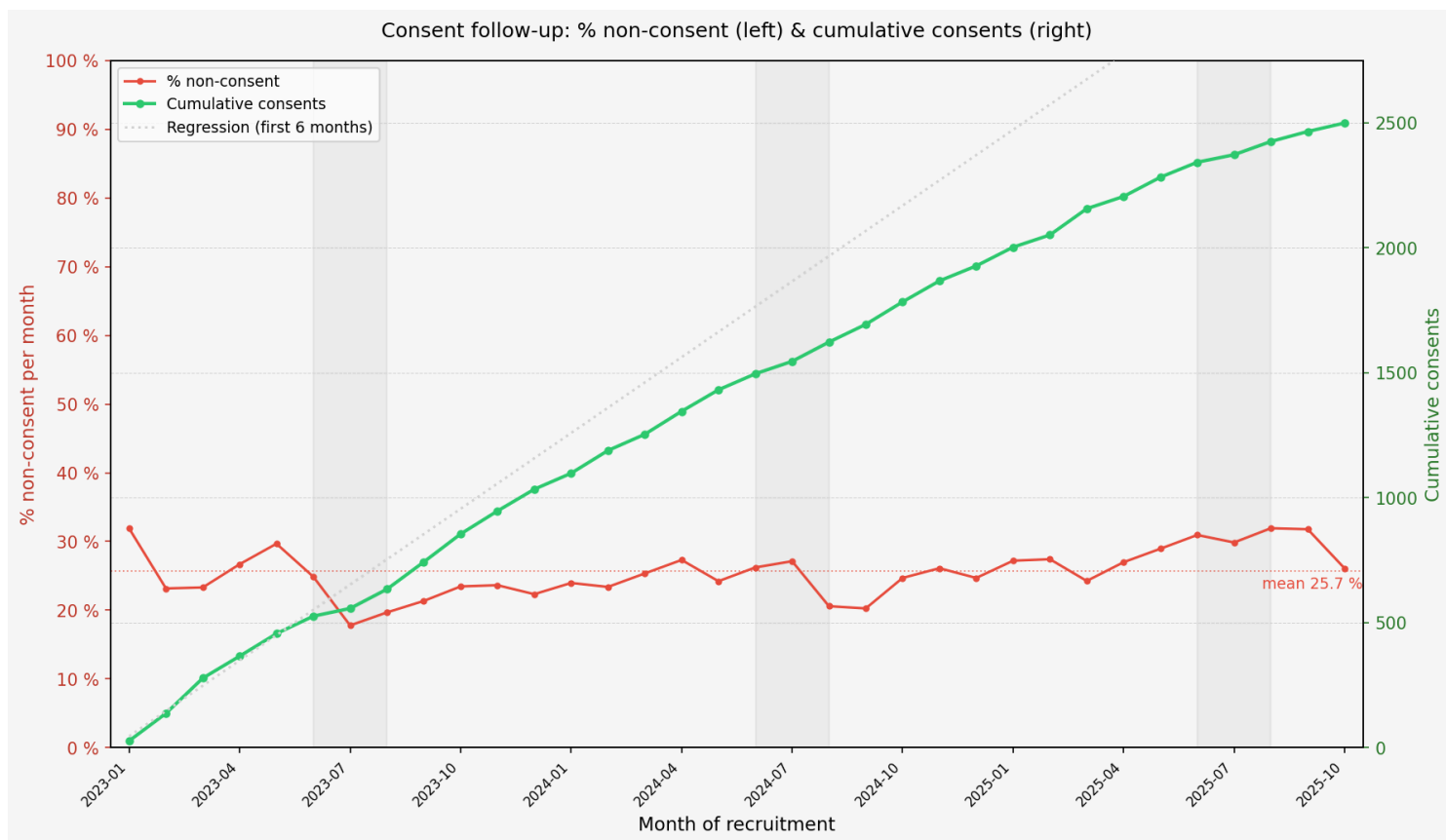


Figure 3

Consent during recruitment period

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