Can Systematic Implementation Support Improve Program Fidelity by Improving Care Providers' Perceptions of Implementation Factors? A Cluster Randomized Trial

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Abstract

Background: Investigations of implementation factors are recommended to better understand and address inadequate implementation outcomes. Little is known about the relationship between implementation factors and outcome, especially in later phases of an implementation effort. The aims of this study were to assess the association between implementation success (measured by program fidelity) and care providers' perceptions of implementation factors during an implementation process and to investigate whether these perceptions can be affected by systematic implementation support.

Methods: Using a cluster-randomized design, mental health clinics were drawn to receive implementation support for one (intervention) and not for another (control) of four evidence-based practices. Program fidelity and care providers' perceptions (Implementation Process Assessment Tool questionnaire) were scored for both intervention and control groups every sixth month for 18 months. Assessments and group differences were tested by means of descriptive statistics (mean, standard deviation and confidence interval) and linear mixed effect analysis.

Results: Including 33 mental health centres or wards, we found care providers' perceptions of a set of implementation factors to be associated with fidelity but not at baseline. After 18 months of implementation effort, fidelity and care providers' perceptions were strongly correlated (B(95% CI)= .7 (.2, 1.1), p= .004). Care providers perceived implementation factors more positively when implementation support was provided than when it was not (t(140)=2.22, p=.028).

Conclusions: Implementation support can facilitate positive perceptions among care providers, which is associated with higher program fidelity. To improve implementation success, we should pay more attention to how care providers constantly perceive implementation factors during all phases of the implementation effort. Further research is needed to investigate the validity of our findings in other settings and to improve our understanding of ongoing decision-making among care providers, i.e., the mechanisms of sustaining high fidelity of recommended practices.

Trial registration: ClinicalTrials.gov Identifier: NCT03271242 (registration date: 05.09.2017).

Background

Implementing new knowledge into existing practices has been a challenging task for health care services for many years [1]. To improve implementation success, we need more guidance on how implementation is accomplished and sustained [2, 3]. Most implementation efforts make use of data on implementation outcomes, such as fidelity scores, to monitor the progression and achievement of implementation [4]. However, these data cannot inform us about why the implementation progression is incomplete or how we should address these issues to improve implementation outcomes. The existing literature suggests several implementation factors, i.e., interrelated, coexisting moderators for implementation outcome to explain implementation [2, 5]. However, the evidence is limited, and as stated by Kelly and colleagues, "There is minimal evidence available to support planners in how best to address (implementation factors)

deficits once they are identified" [5]. Evidence of implementation factors that are both associated with implementation outcomes and found to be affected by systematic implementation support is warranted to foresee challenges and effectively intervene guided by these factors.

Few of the existing, theoretically founded, implementation factors have demonstrated reliable associations with implementation outcomes [2, 6–8]. There may be several methodological reasons for this apparent lack of association. First, many of the constructs are investigated one by one rather than as a set of interrelated factors. According to Caudoir et al., "there are many "moving parts" to consider that can ultimately determine whether implementation efforts succeed or fail." [6]. Complex interventions, such as implementation, should be investigated as a set of interacting factors [9, 10]. Second, many investigations are based on the assumption that sufficient preparedness prior to implementation implies success. Examples are organizational readiness for change [7, 11] and clinicians' attitudes towards evidence-based practice [12]. However, stages of change theory by Prochaska, Rogers and others describe stages of orientation, insight and acceptance to be ready for making and maintaining the change and that these stages are iterative [13–15]. Care providers constantly assess pros and cons and may reconsider their involvement in the change. A more process-based approach to readiness than the existing definition as a prestate is recommended [16]. Investigations of implementation factors solely before entering the active implementation phases do not consider the continuous exposure of contextual factors under which care providers decide whether they should continue implementation [17]. Third, many factors are investigated by observations. Examples are the model for understanding success in quality (MUSIQ) [18] and stages of implementation completion (SIC) [19]. External observation is not in line with theories that define alteration of behaviour as a social construct, i.e., an experience by those making the change. To explain change in behaviour, learning theories and diffusion of innovation theory highlight the change agents' sense of support, gains and obstacles, rather than objective observation [13, 20]. Finally, there are methodological limitations to existing research on implementation factors. A majority of studies employ retrospective, uncontrolled designs or qualitative investigations [2]. To reveal implementation factors' relevance for fidelity and other implementation outcomes and whether systematic implementation support can impact these factors, we need a randomized controlled design with longitudinal data gathering during an implementation effort.

We aimed to assess the associations between fidelity and care providers' perceptions of a set of implementation factors and investigate whether these perceptions can be affected by systematic implementation support. We wanted to investigate these associations and impacts at different points in time during an implementation effort.

Methods

Using a cluster-randomized controlled trial design, specialist mental health units were invited to implement recommended practices for the treatment of psychosis. Each clinical unit chose two of four predefined practices they intended to implement and was randomized to implementation support for one practice (intervention arm) and not for the other (control arm). We prospectively measured health

professionals' perceptions of the implementation effort and the units' degree of implementation every sixth month during an 18-month period. This was measured for both the practice they received implementation support for and for the control in each clinical unit.

Sample and randomization

This study was conducted within Norwegian specialized mental health care. Specialist mental health care units, i.e., Community mental health centres and mental health hospital departments, in six public health trusts in 2016, were invited by the research group to take part in a study to improve compliance with the national clinical guideline for the treatment of psychosis. Four evidence-based practices described in the guideline were chosen by the project group after a survey among the included units. These were practices or programs for antipsychotic medication management (MED), physical health care (PHYS), family psychoeducation (FAM), and illness management and recovery (IMR). Using pairwise randomization, each included clinical unit was represented in both the intervention group and the control group. Each unit was assigned to receive implementation support for one of the two practices they had chosen and not for the other. Earlier investigations from this trial have shown that the implementation support intervention had a significant positive impact on the fidelity scores [21].

Assuming a similar increase in fidelity scores as found in the US study by Bond and colleagues [22], using a two-tailed significance level at .05 and 90% power, we estimated that eight sites in each arm for each practice were sufficient.

To represent each unit, a purposive sample of care providers who their manager saw as particularly important for the clinical practice of psychosis treatment constituted the sample of IPAT responders. We decided a cut-off of three or more responders per unit as inclusion criteria for this study. The cut-off was set based on logic reasoning balancing generalizability to the unit and representation of a variety of units. At the instance of the first data collection (baseline), the clinical units were recently informed about which practice they would receive implementation support to enable some preparations, such as deciding who should attend the clinical training.

The intervention (implementation support)

The intervention bundle was designed to affect care providers' readiness and engagement, and included tools and measures described in the literature [22, 23] and more innovative measures. It consisted of clinical training, implementation facilitation, and assessment and feedback every sixth month on level of compliance to recommended care and health professionals' anonymous report on how they perceived the implementation effort. The clinical training included workshops with lectures and meeting colleagues from across the country, lasting one day for medication and physical health practices and 2 x 2 days for IMR and family support practices. For the IMR practice and the family support practice, the clinicians were offered additional supervision by a clinical expert on the practice. For IMR, this was offered every week for the first six months and every second week for the next six months. For the family support it was offered every other week for six months and then monthly for the next six months. A website with further

educational material and tools was made available for the four practices. The implementation facilitation included support and training to enhance positive perceptions of the implementation effort i.e., planning and using tools and methods such as flow charts, process measuring and team activities to improve shared understanding and accountability. The units were offered one meeting with trained implementation facilitators every second week for the first six months and then once a month for one year. The implementation facilitators were trained by implementation experts in the project to recognize and interpret care providers' perceptions of facilitating and hindering factors for implementation, measured by the implementation process assessment tool (IPAT), and to suggest tools and methods to improve these perceptions and thereby make implementation teams successful. They had relevant clinical experience and training but were not clinical experts on any of the four practices to be implemented. The intervention included assessments and feedback on the unit's degree of compliance with the practice, measured by fidelity scales, and on clinicians' perceptions of the implementation effort, measured by the Implementation Process Assessment Tool (IPAT) questionnaire, every sixth month for 18 months. The feedback on IPAT-scores were provided to the manager, the implementation team and the implementation facilitator at each clinical unit shortly after each measuring together with a short report to help interpretation and suggest interventions to improve low scores. Please see Fig. 1.

Measures

Fidelity scales were used to measure the implementation of each of the four practices. The fidelity scales and their psychometric properties are described in earlier papers [24–27]. An assessment team of two clinicians trained to use the fidelity scales conducted the scoring. They interviewed clinicians and managers at the unit, reviewed documents (e.g., procedures and data on performance) and conducted audits of ten randomly selected patient records for patients receiving psychosis treatment. The 13–17 items of the fidelity scales were rated on a scale from 1 (not implemented) to 5 (perfectly implemented). The unit of analysis for fidelity score is the clinical unit, defined by the mean of the items.

Health professionals' perceptions of the implementation factors were measured by the Implementation Process Assessment Tool (IPAT) [28]. The IPAT questionnaire is theoretically based on constructs defined in the Consolidated Framework for Implementation Research [29], including Readiness for change [30] and Stages of change [13, 14, 31]. In the theoretical model for the IPAT construct, outer- and inner-setting factors, intervention characteristics and characteristics of individuals affect individuals' and teams' perceptions of and reactions to the situation. Their reactions appear as progression of stages of change that interact with their perceptions of the situation [28]. The 27 items measures progression in the stages of change, individual activities and perceived support, collective readiness and support, and individual perception of the intervention. Examples of items are "*I have discussed with colleagues how this new practice will work in our unit.",*" *I believe the patient will benefit from the improvement." and "We who work here agree that we have a potential for improvement in [new practice]".* The questionnaire is distributed to a purposive sample of health professionals central to the provision of care in question. The Likert scale from 1 (not agree/not true) to 6 (= agree/correct) for each of the 27 items reveals variation between respondents and between units. The internal consistency for the total scale and for each of the four

underlying constructs was found to be high (Cronbach's alpha > .83) [28]. The IPAT's unit of analysis is the clinical unit and is represented by the mean of responders from the unit.

Fidelity and IPAT were both scored four times during an 18-month period, i.e., at baseline, 6 months, 12 months and 18 months.

Analyses

Descriptive methods (mean, percent and standard deviation) and confidence intervals were used to describe the IPAT responders and the IPAT and fidelity scores. The associations between care provider perceptions (IPAT scores) and fidelity scores at each time point were explored by linear mixed effects models for fidelity scores depending on IPAT adjusted by group (support/no support) and the random intercept for practice and unit. These models were estimated both with and without the interaction between IPAT and group, i.e., enabling or disabling different slopes for the groups. The effect of support on IPAT was assessed using the linear mixed effects model for IPAT depending on group, time and the interaction between group and time adjusted by random intercept for cases, practice and unit with simple contrasts in time domain. The interaction term in these models estimates the change of differences between groups from baseline. All analyses were done both for IPAT total and the four factors of IPAT, the significant level was set to 0.05. Since the primary analysis was only the effect of support on IPAT total, no adjustment for multiple testing was necessary.

Statistical analyses were conducted using SPSS 26.0 (IBM Corp., Armonk, NY) and R 4.0 [32], and MATLAB 2020b (Mathworks Inc., Natick, MA) was used for graphics.

Results

Sample, Implementation Process Assessment Tool (IPAT)-scores and fidelity scores

Thirty-three of 39 clinical units were included. Following the inclusion criteria of three or more IPAT responders per unit, we excluded six units at baseline, eight at 6 months, sixteen at 12 months and eighteen at 18 months. Please see Fig. 2. The clinical units represented six health trusts in both rural and urban parts of Norway. Twenty-one were community mental health centres, and 13 were hospital units (e.g., forensic wards or specialist units for the treatment of psychosis).

As shown in Table 1, the number of valid responses decreased from 696 (response rate: 59%), representing 33 units at baseline, to 326 (response rate: 30%), representing 21 clinical units at eighteen months. The distribution of the IPAT respondents' gender and profession reflects mental health care units in the present setting. In accordance with the inclusion criteria of "essential clinicians", the majority of respondents were trained clinical experts within mental health care.

Table 1
Description of the respondents on the IPAT score at baseline, 6, 12 and 18 months. *At 6 months 15% missing on description of respondents.

		Baseline	6 months*	12 months	18 months
No. valid responses (response rate)		696 (59%)	464 (39%)	306 (27%)	326 (30%)
Mean (SD) no. respondents per unit		9.8 (4.1)	6.8 (4.6)	4.8 (2.6)	6.5 (3.5)
Description respondents					
Gender	Men	23%	20%	22%	22%
	Women	77%	65%	77%	78%
Profession	Medical doctor	8%	7%	8%	9%
	Nurse	57%	50%	62%	65%
	Psychologist	10%	7%	5%	6%
	Social worker	7%	6%	7%	7%
	Other	18%	15%	18%	13%
Amount health professionals specialized in mental health care		63%	57%	72%	80%

The mean IPAT scores per unit at baseline were higher for the intervention group (mean (CI) = 3.66 (3.45, 3.87) than for the control group (mean (CI) = 3.31 (3.12, 3.49). The fidelity scores were low for both the intervention arm (mean (CI) = 1.77 (1.49, 2.05)) and the control arm (mean (CI) = 1.82 (1.56, 2.07)). The IPAT and fidelity scores improved during the study period for both groups, yet a significantly larger improvement was seen where implementation support was provided compared to the control arm. (See Table 2).

Table 2
Mean fidelity scores and mean IPAT scores (mean (95% Confidence Interval)) per included unit for intervention (implementation support) and control-arm at baseline, 6, 12 and 18 months.

	Fidelity		**Implementation Process Assessment Tool (IPAT)**	
	Supported	*Control*	*Supported*	*Control*
Baseline (mean (CI)) (N = 33 for supported, N = 32 for control)	1,77 (1.49, 2.05)	1,82 (1.56, 2.07)	3,66 (3.45, 3.87)	3,31 (3.12, 3.49)
6 months (mean (CI)) (N = 31)	3,11 (2.74, 3.48)	1,86 (1.56, 2.16)	4,24 (3.98, 4.50)	3,72 (3.47, 3.97)
12 months (mean (CI)) (N = 23 for supported, N = 22 for control)	3,41 (2.90, 3.92)	2,02 (1.65, 2,39)	4,21 (3.88, 4.53)	3,54 (3.20, 3.88)
18 months (mean (CI)) (N = 21)	3,69 (3.15, 4.22)	2,38 (1.91, 2.86)	4,29 (3.96, 4.61)	3,44 (3.10, 3.77)

Association between IPAT and fidelity

As shown in Fig. 3, health care providers' perceptions of the implementation effort (IPAT scores) and achieved implementation (fidelity score) were found to be significantly correlated at 12 and 18 months. The linear mixed effect model, adjusting for unit and practice, revealed a strong association at 18 months (B (CI) = .7 (0.2, 1.1) p = .004). At 12 months, the association was moderate (B(CI) = 0.4 (0.0, 0.7), p = .045). The analysis indicated no, or even negative, correlation at baseline; however, this was not significant.

Implementation support's impact on health professionals' perceptions of the implementation effort

Health care providers reported higher scores on how they perceived the set of implementation factors when implementation support was provided than when not. Figure 4 displays the results of the linear mixed effect analysis, adjusting for time and type of practice implemented, confirming the positive association between implementation support (intervention) and IPAT-score at 18 months (t(140) = 2.22, p = .028). The confidence intervals for mean indicate significant higher IPAT-scores in the intervention groups compared to control groups at all times of measurements (see Table 2.) Importantly, the differences in IPAT-scores were present already at baseline when the clinical units knew for which practice they would receive support for.

Discussion

In the present study, we found fidelity to be positively correlated with care providers' perceptions of the implementation and that these perceptions can be affected by systematic implementation support. The correlations between fidelity and IPAT score were strongest late in the implementation process and were not present at baseline. The care providers perceived the implementation for the practice they received structured implementation support for more positively than the control practice.

A relationship between how care providers perceive the implementation effort and implementation outcome, as we found, is in line with well-known theories and frameworks such as Readiness for change, Stages of change and CFIR suggest [15, 18, 29, 33, 34]. However, we found the implementation factors and outcome to be associated later in the implementation process and not at onset. Our findings are in contrast to the literature emphasizing the investigation of facilitating factors only prior to an implementation effort [7, 18, 35]. They indicate that a more process-based approach to the readiness concept, as suggested by Stevens, among others [16], can be beneficial to understanding implementation. The changing IPAT scores during the period of 18 months also suggest that health professionals assess the situation during all phases of the implementation to decide if they will implement and sustain the new practice. This is in line with Nilsen, arguing that the progression of the implementation process and health professionals' perceptions are mutually affected and that actions are mutually affected in a context [17, 36]. According to Stevens, the assumption that it is sufficient to establish readiness at baseline fails to understand the influence of context over time on individuals' cognitive and affective evaluation and response [16]. Furthermore, our results are in line with complex intervention theory highlighting mutual interactions between intervention and context factors [9] and with evidence for repeated feedback's impact on maintaining engagement during the implementation process [37]. Our results suggest that care providers' perceptions and implementation outcomes are mutually affected, creating a positive or negative spiral of improvement success or failure, as described by Øvretveit [38].

The implementation literature states that systematically developed intervention bundles can affect health professionals' engagement and implementation outcomes [29, 39]. The intervention in the present study was designed to affect the same construct of care providers' individual and collective readiness and engagement as the IPAT questionnaire intend to measure. It combines several recommended interventions, such as continuous measurement and provision of feedback, clinical training, implementation training and team support [1, 39–41]. Our finding of a significantly higher score on the IPAT scale when implementation support was provided compared to when not was therefore expected. What we believe to be innovative is the measurement of and feedback on how the implementers experience the implementation effort. Responding to the questionnaire may introduce reflections about effective implementation among the responders, and the manager can gain insight into the facilitation needs. We combined this with guidance from implementation facilitators trained to support team activities to meet the needs revealed by the IPAT scores. Tailoring implementation support to the present needs of the implementers is emphasized in the literature [1]; however, we cannot state which part of the intervention was the most effective. Interestingly, we also found the IPAT score to be higher for the

practices the units knew they would get support for before the onset of systematic implementation support. We believe this is best understood by readiness theories recognising the importance of self-induced initial preparation and collective tuning in on the forthcoming implementation effort [42].

Few implementation factors are tested for their associations with implementation outcomes. The review by Chaudoir et al. found only one study where explanations for variation in fidelity were investigated [6]. In the present study, we employed a questionnaire based on a combination of theories and a framework for implementation [28]. Given the complexity of implementation, we believe that the extraction of prominent factors from a set of theories is more likely to explain implementation than scales based on single theories. The significant correlation we found between the IPAT score and fidelity indicates that the questionnaire is well suited for investigating the “why” in implementation.

The present study used a cluster-randomized longitudinal design including a large sample of clinical units followed for 18 months. We gathered data four times on implementation factors and -outcome for both the intervention and the control arm. Most investigations of the implementation process have used a retrospective design and/or qualitative methods, implying a risk of bias related to the informants’ and researchers’ recollection and insight into the implementation process [2, 43]. The repeated measurement we conducted every sixth month enabled an investigation of associations between perceptions and actual change to practice in different phases of the process that qualitative or pre-post design cannot. The design, where each clinical unit was assigned to both intervention and control arms for two practices they had chosen to implement, reduced the risk of bias. However, a risk of spillover effects from the intervention to the control arm is present, which implies that we may underestimate the effect of the intervention.

Each clinical unit chose two of four practices and was drawn to receive support for only one. Logically, we expect the clinical units to choose practices they need to implement. The generally low score initially indicates that this was true. Our results and conclusions should be interpreted as true when implementing a practice that the clinical unit believes to be beneficial for them. We do not know to what degree our results are valid for situations where clinical units are obliged to implement a practice they have not chosen themselves.

The study was conducted in Norwegian specialist mental health care and regards the implementation of evidence-based practices for patients suffering from psychosis. The sample represents typical multiprofessional clinical units from urban and rural areas of Norway. The IPAT is based on international acknowledged literature and is expected to be valid for similar Western health services. It is developed for health care services in general but has only been tested within mental health care yet. The generalizability of the present study’s results and conclusions to health services for other patient groups or to other countries is unknown.

Limitations

Concerns regarding response rates, statistical power and choice of statistical analyses should be considered when interpreting the results of the present study. The response rates decreased during the 18-month period. We do not know to what degree the mean score per unit represents the invited sample, but the distribution of represented professions lends support for representability. Implementing four different practices measured by four unique fidelity scales reduces the statistical power compared to investigating only one or two practices, implying a risk of type II error (not detecting an existing association). The IPAT scores were higher in the intervention group compared to the control group at baseline. This may indicate that the units gave priority to the practice they knew they would get support for and were able to self-induce steps to improve care providers' readiness before onset of the defined intervention. Preparatory steps' impact is of great interest to understand implementation, but was not defined in the study as a part of the intervention and therefore adjusted for in the analysis. Retrospectively, we can see that we underestimated the impact of the minor initial preparatory steps we did. No measures were taken to limit engagement in the control practice, which may have reduced the differences between intervention and control arms. Given the strong evidences for the clinical practices that were implemented, we believe implementation success (program fidelity) can constitute a valid intermediate outcome for patient outcomes, however, this was not investigated in the present study.

Conclusion

The present study indicates that implementation can be facilitated by improving how care providers perceive the situation of implementation and that these perceptions can be improved by systematic implementation support. The results suggest less emphasis on preparedness prior to implementation and more emphasis on care providers' continuous assessment of pros and cons for implementation and how we tailor the support to meet these changing needs. The stronger association of implementation factors and implementation outcome with larger differences between the intervention and control groups at 18 months after the onset of implementation support highlight the importance of long-term planning and facilitation to stabilize the new practice. However, further research is needed to understand how we can provide efficient implementation support. New studies should investigate whether some implementation factors are more important than others at different phases of the implementation process and whether our results can be generalized to the implementation of other practices and in other health services.

Abbreviations

IPAT
Implementation process assessment tool (questionnaire)
IMR
Illness management and recovery (practice)
FAM
Family psychoeducation (practice)
MED

Anti-psychotic medication (practice)
PHYS
Physical health care (practice)

Declarations

Ethical Approval and Consent to participate

The study was approved by The Regional Committee for Medical and Health Research Ethics in Southeastern Norway (Reg. No. REK 2015/2169, first approval 17.12.2015) and the Data protection officer for each health trust. We followed the principles in the Declaration of Helsinki. The study followed the Consort Extension guidelines for cluster randomized trials and the StaRI checklist for implementation studies. Both completed checklists are submitted together with the manuscript. Written informed consent was obtained from all participants. They received written information about the study and contented by responding to the questionnaire.

Consent for publication

Not applicable.

Availability for data and materials

The datasets generated and analysed during the current study are not publicly available due to ongoing investigations using the same dataset but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no conflicts of interest. The IPAT questionnaire can be used free of charges.

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Authors’ contributions

The first (MH) and last (TR) authors participated in all steps of the study. Planning and facilitating of the large implementation study was conducted by MH, GB, IJ, KH, BS, VA, TSH and TR, whereas JØ, EH, JA and EB were particularly involved in planning of the present study. All authors contributed to the publication of the results and approved the final version.

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Authors' information

Not applicable.

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Figures

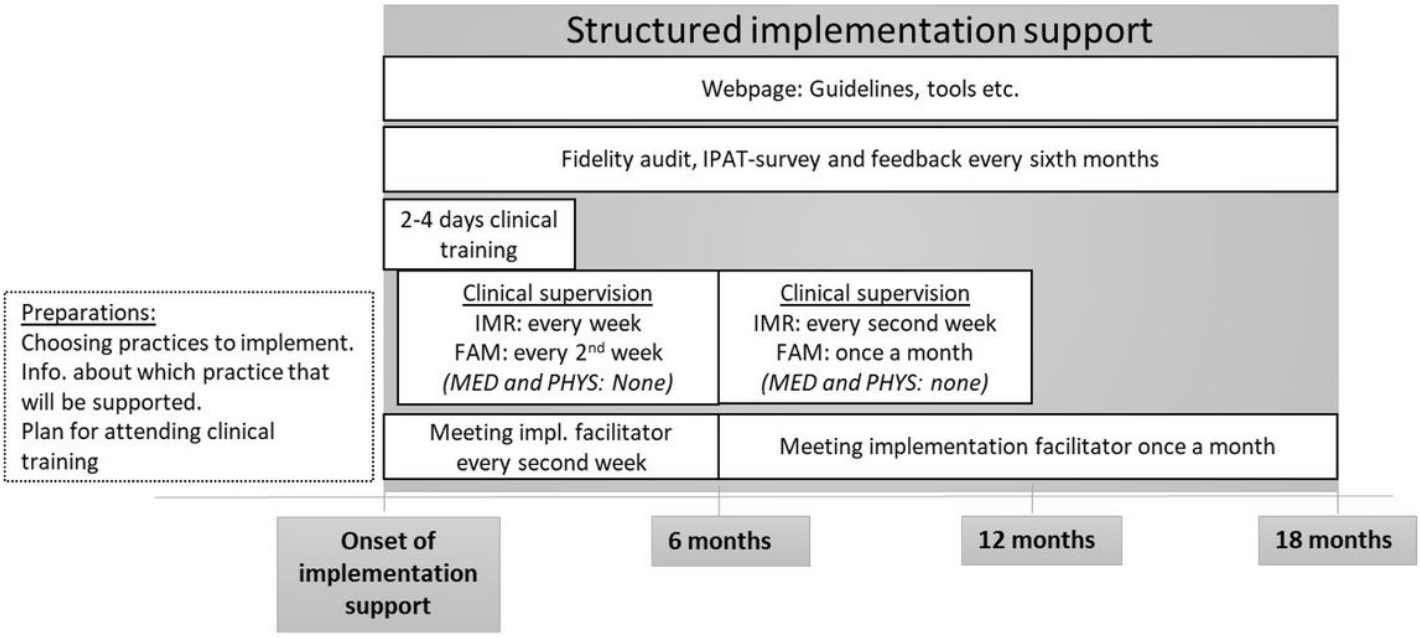

Figure 1

Description of the implementation support (intervention) displayed on a timeline for when and how long each intervention was provided for each of the four practices (IMR=Illness Management and Recovery practice, FAM =family supportive practice, MED= antipsychotic medication, PHYS=Physical health support).

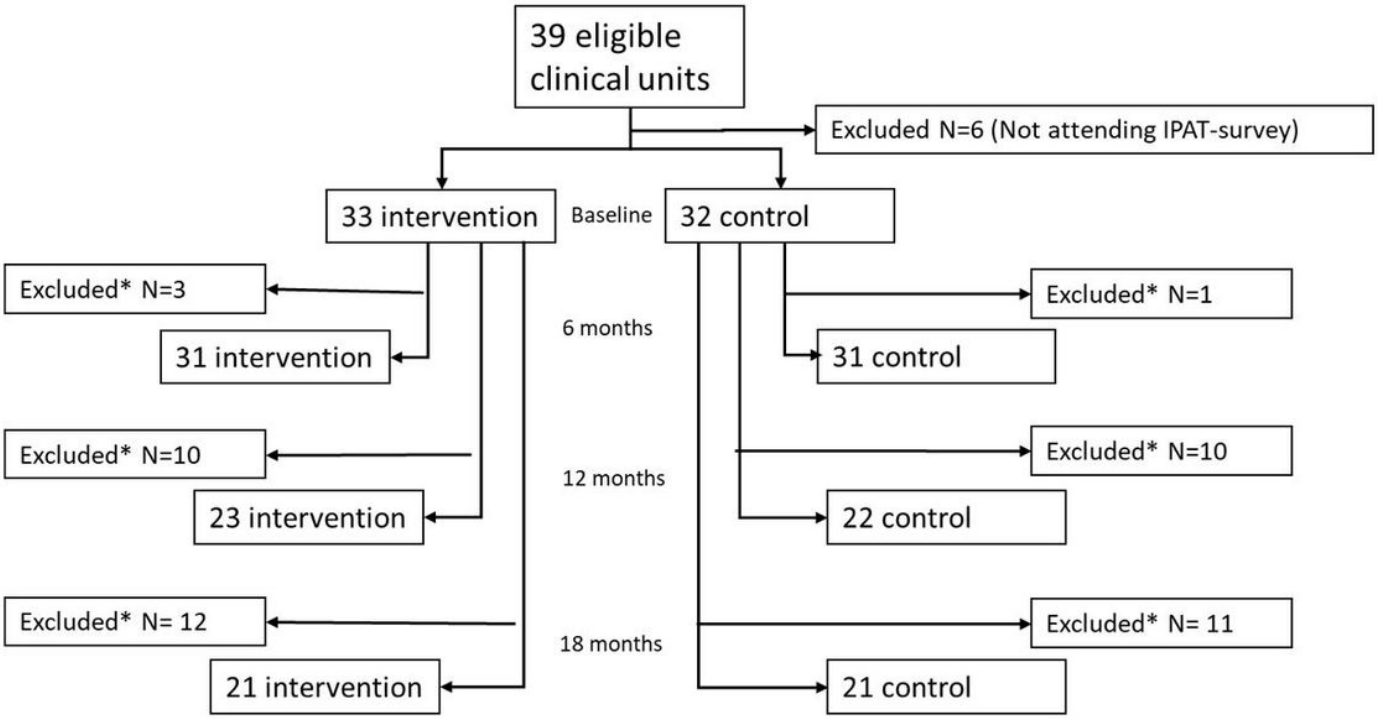

Figure 2

Flow diagram displaying the sample and exclusion during the 18 months period.

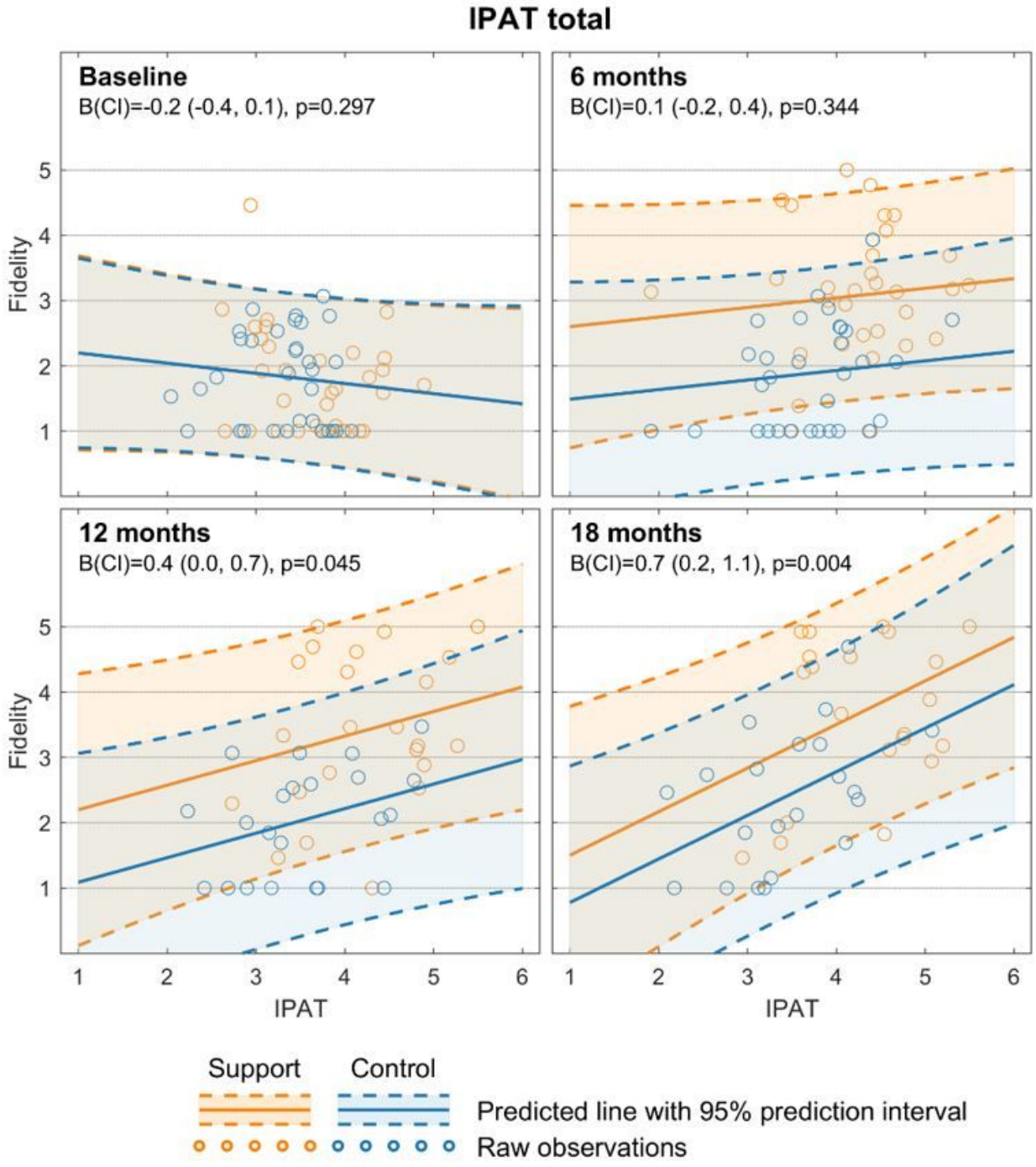

Figure 3

Correlations between the Implementation Process Assessment Tool score and fidelity score for the intervention and control groups every sixth month. Linear mixed model analysis model with time adjusted IPAT-score as fixed effect and type of practice as random effect.

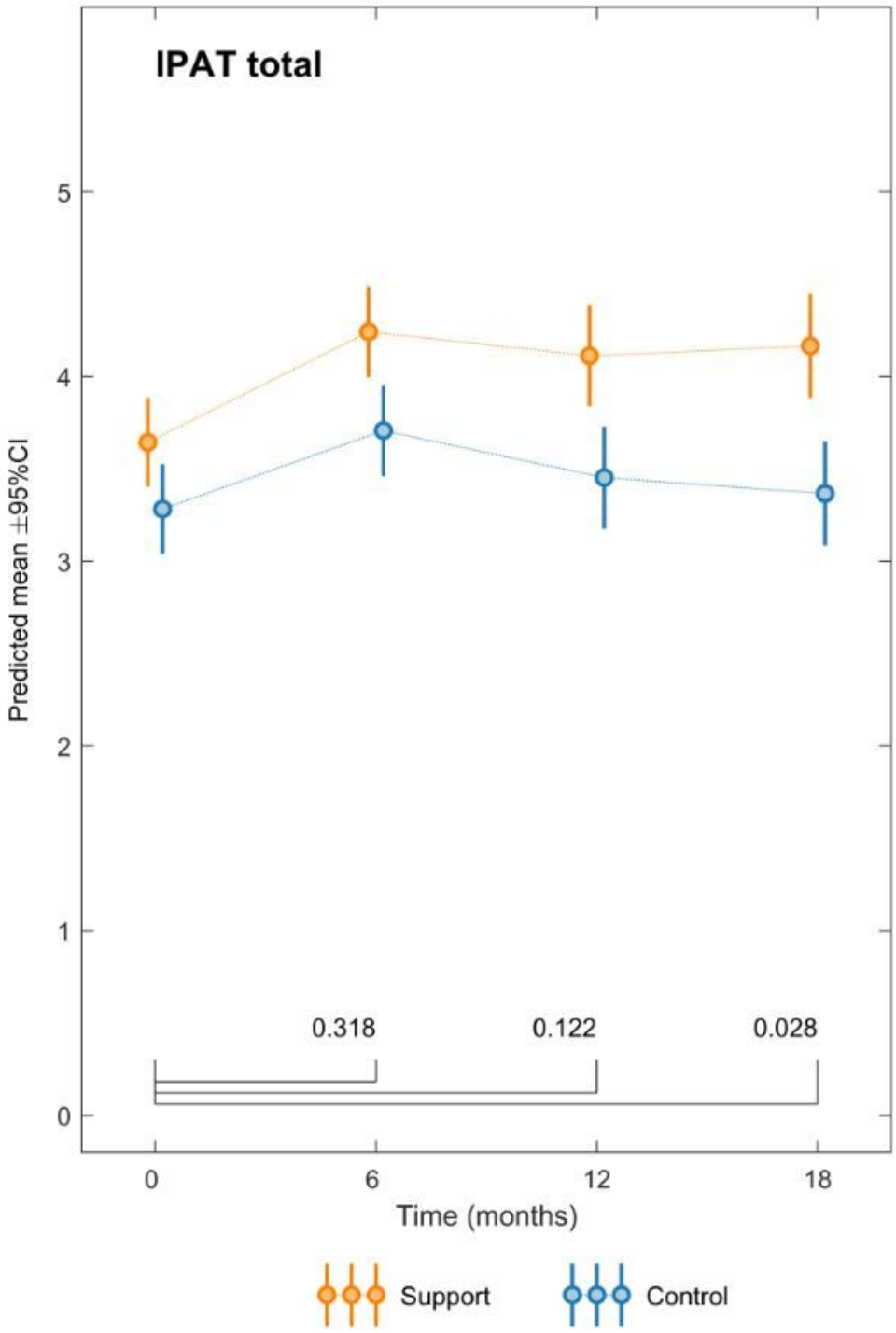

Figure 4

Comparison of IPAT-score (total and each of the four sub-scales) between intervention and control groups, adjusted for time and practice implemented, using a linear mixed model. Means and standard deviations (SD) are displayed in the figure (orange for intervention and blue for control group).