A Stepped-Wedge Randomized trial Investigating the Effect of the Leadership and Organizational Change for Implementation (LOCI) Intervention on Implementation and Transformational Leadership, and Implementation Climate

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Research

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Abstract

Background: This study evaluates the Leadership and Organizational Change for Implementation (LOCI) strategy and its effect on implementation leadership, transformational leadership, and implementation climate.

Methods: A stepped wedge cluster randomized trial enrolled 47 first-level leaders from child- and adult-specialized mental health clinics within Norwegian health trusts across three cohorts. All therapists (*n* = 804) received training in screening of trauma exposure and posttraumatic stress, and a subgroup (*n* = 249) of therapists received training in evidence-based treatment methods for posttraumatic stress disorder (PTSD). First-level leaders and therapists were asked to complete surveys at baseline, 4, 8, 12, 16, and 20 months assessing leadership and implementation climate. General linear mixed effects models were used to investigate whether engagement in the LOCI strategy would lead to greater therapist-rated scores on implementation leadership, transformational leadership, and implementation climate.

Results: There was a significant increase in therapist-rated implementation and transformational leadership as well as implementation climate after the leaders were introduced to the LOCI strategy. This increase was sustained at all measurement time point compared to non-LOCI conditions which demonstrated a steady decrease in scores before LOCI was introduced.

Conclusions: The LOCI strategy can develop better transformational and implementation leadership skills as well as contribute to a more positive implementation climate to enhance successful evidence-based practice implementation. Thus, LOCI can help leaders create an organizational context conducive for effective EBP implementation.

Trial registration: NSD 60036/3/LH, NSD 60059/3/OOS

The full trial protocol can be accessed from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6417075/

Contributions To The Literature

1. This study provides new knowledge on how to improve staff-rated leadership and climate to enhance effective implementation of evidence-based practices.
2. The Leadership and Organizational Change for Implementation (LOCI) has showed positive effects in US contexts. This study expands the implementation research field by demonstrating the utility of this implementation strategy in a Norwegian mental health setting.
3. Therapists´ experiences of leadership and implementation climate decreased over time following training of therapists in evidence-based practices while significantly increasing when LOCI was introduced. This suggests that clear implementation strategies are vital to achieve good leadership and a positive implementation climate.

Introduction

Leadership has consistently been highlighted as important for achieving successful evidence-based practice (EBP) implementation and sustainment (1–4). Leader behaviors are associated with a range of positive outcomes at multiple health system and organization levels (5), such as fostering positive staff attitudes (6), lowering staff turnover (7), improving organizational climate and therapeutic alliance (8, 9), and increasing patient satisfaction and quality of life (10, 11). Thus, leadership development is promising for facilitating improvements in the delivery of healthcare services. Although leader development is a multi-billion-dollar industry globally with many leader development programs available (12, 13), some lack research evidence (14), and many fail to fulfill expectations for improvements in organizational effectiveness (15). In addition, few leader development programs have highlighted specific strategies that organizations and leaders can use to align efforts to improve implementation outcomes. However, there are some strategic approaches that can facilitate more effective leadership development (16). Such approaches, in addition to research and evaluation to support their effectiveness, are needed to improve leadership for EBP implementation in health care settings.

The Leadership and Organizational Change for Implementation (LOCI) strategy (17, 18) is a leader development program focused on implementing specific evidence-based practices (EBPs) in healthcare services. LOCI serves as an implementation strategy that aims to build leadership skills and create a positive strategic organizational climate to support effective and sustained implementation of EBPs (see full description of LOCI; 18, 19). LOCI targets first-level leaders responsible for the supervision of individuals providing direct services, while simultaneously including executive management to facilitate an aligned implementation approach (20). By training first-level leaders in LOCI, it is hypothesized that they will exhibit more transformational and implementation leadership. In addition, LOCI encourage the development of systems and procedures to support EBP implementation. Consequently, as employees experience their leadership's support of implementation and the systems and procedures are aligned around implementation effectiveness, they are more likely to report a positive and supportive unit level implementation climate (18, 20, 21).

LOCI utilize two central leader development theories. *The Full-Range Leadership Model (FRL)* targets general leadership skills and behaviors that create a shared vision and positive work environment, so that staff may feel emotionally and intellectually engaged. FRL is well researched and validated globally (22) and involves transformational and transactional leadership, as well as non-leadership (e.g., laissez-faire). Transformational leaders perform four distinct behaviors: inspirational motivation, idealized influence, intellectual stimulation, and individualized consideration. Transformational leadership has shown to be favorably related to a variety of employee and organizational outcomes, such as employees' job satisfaction (23), perceived job demands and turnover intentions (7), organizational climate and work engagement (23, 24), as well as the adoption, use, and success of EBP implementation (25). Although the primary focus of LOCI is to improve transformational leadership, transactional leadership is also included. Specifically, the contingent reward dimension of transactional leadership is related to a leader's ability to manage and motivate their employees through appropriate rewards (22). *Implementation leadership*

theory hypothesizes that leaders will achieve better implementation outcomes when they are proactive, knowledgeable, supportive, and perseverant with regard to the implementation of the specific EBP (21). Furthermore, LOCI also builds on theories on *implementation climate*, defined as the extent to which employees share perceptions that the adoption and implementation of the EBP is expected, supported, and rewarded within their organization (26, 27). Implementation climate has been shown to mediate the effect of implementation leadership on therapists' use of EBP (28).

LOCI has been tested in one study (17), and three ongoing randomized controlled trials (18, 29) are under way in the United States, funded by the US National Institutes of Health. Preliminary results have shown that LOCI is feasible and acceptable (17) and is related to improved staff-rated leadership and implementation climate for EBP implementation (17, 18) (30). Although there has been increased interest in approaches to leadership in implementation research and practice (31–33), there is a need for testing the effectiveness of strategies such as LOCI on implementation and transformational leadership and implementation climate in a variety of settings. Such knowledge can facilitate successful EBP implementation and sustainment. This is the first study to examine the effect of LOCI outside of the USA, with a potential to strengthen its generalizability. Our aim is to test the effect of LOCI on implementation and transformational leadership, and implementation climate compared to the non-LOCI condition. Based on theory and empirical evidence, we hypothesize that:

H1: Implementation leadership will improve more in the LOCI as compared to the non-LOCI condition.

H2: Transformational leadership will improve more in the LOCI as compared to the non-LOCI condition.

H3: Implementation climate will improve more in LOCI as compared to the non-LOCI condition.

Methods

The current study utilizes a stepped-wedge randomized design to investigate the effect of the LOCI strategy. Please see the study protocol (19) for further details about the study.

Participants

Participants were therapists (n = 804) with an average age of 43.8, 75.4% were female, and approximately half were clinical psychologists (Table 1). They completed questionnaires addressing implementation climate and general and implementation leadership among first-level leaders (n = 47) who received the LOCI intervention at 43 participating clinics (Table 1).

Table 1
Participant characteristics

	LOCI leaders (N = 47)	Therapists (N = 804)	Overall (N = 851)
Gender			
Women	29 (61.7%)	606 (75.4%)	635 (74.6%)
Men	18 (38.3%)	171 (21.3%)	189 (22.2%)
Education			
Psychology	26 (55.3%)	371 (46.1%)	397 (46.7%)
Medicine	5 (10.6%)	151 (18.8%)	156 (18.3%)
Social worker	8 (17.0%)	60 (7.5%)	68 (8.0%)
Nurse	8 (17.0%)	55 (6.8%)	63 (7.4%)
Other	0 (0%)	89 (11.1%)	89 (10.5%)
Age			
Mean (SD)	49.7 (7.64)	43.8 (11.1)	44.2 (11.0)
Missing	0 (0%)	115 (14.3%)	115 (13.5%)

Procedures

This study was conducted in mental health clinics for children and adolescents and for adults, which were localized within health trusts across Norway. At baseline, all therapists (*n* = 804) in the participating clinics were trained in screening and diagnosing of PTSD (Table 2). In addition, a sub-group of therapists (*n* = 249) received training in three of the most well-documented EBPs for PTSD (34, 35), namely Trauma-Focused Cognitive-Behavioral Therapy (36) for children, and either the Eye Movement Desensitization and Reprocessing (37) or Cognitive Therapy for PTSD (38) for adults. The CT-PTSD and EMDR training consisted of a three-day course followed by 10 hours coaching group calls divided by 2 hours once a month for 5 months. Training and supervision were given by specialists in each of the three EBPs. The TF-CBT training included three days of initial training followed by weekly 1-hour case coaching calls in groups for a year (approximately 40 hours). Following the training, all clinics were eligible to screen patients and provide EBP for PTSD.

Table 2
Stepped-wedge study design

Cohort	Time periods									
	Measure 1	Training*	Measure 2	Training*	Measure 3	Training*	Measure 4	Training*	Measure 5	Train
	Jul 2018	Sep 2018	Dec 2018	Jan 2019	Apr 2019	May 2019	Jul 2019	Sep 2019	Dec 2019	Jan 2020
I	Non-LOCI	EBP + LOCI start-up	LOCI implementation phase	LOCI booster	LOCI implementation phase	LOCI booster	LOCI implementation phase	LOCI graduation	Sustainment phase	
II	Non-LOCI	EBP	Non-LOCI	LOCI start-up	LOCI implementation phase	LOCI booster	LOCI implementation phase	LOCI booster	LOCI implementation phase	LOCI gradu
III	Non-LOCI	EBP	Non-LOCI		Non-LOCI	LOCI start-up	LOCI implementation phase	LOCI booster	LOCI implementation phase	LOCI boos

*Training:

Training in EBP: Training therapists in evidence-based screening and treatment methods for PTSD.

Training in LOCI: Training leaders in general and implementation leadership, and implementation climate (start-up meeting, booster meetings, and graduation

Forty-eight first-level leaders from 48 different child (n = 26) and adult (n = 22) clinics were randomized by a computer algorithm into one of three cohorts, each initiating training in LOCI at three different time points as indicated in the stepped-wedge (Table 2). The stratified randomization was made based on the following variables: number of therapists per clinic, co-localization of more than one clinic, number of therapists to receive training in each of the EBPs, number of therapists per LOCI leader, total number of inhabitants for each randomization unit, number of municipalities or districts for each unit, and number of inhabitants within the health trust served by the participating clinics. Power calculation based on 48 clinics showed that a difference at a little below .4 standard deviations will be detected with 80% power. The random allocation and enrollment and assignment of participants were conducted by the research group.

Four clinics dropped out from the project during initial phase of LOCI (one from cohort 1, two from cohort 2, and one from cohort 3) and were excluded from the main analysis. Linear mixed effects analysis with clustering on clinics demonstrated that there were no significant differences in scores ($p \geq 0.564$) between therapists in dropout and participating clinics in terms of baseline scores on implementation leadership, transformational leadership, or implementation climate. The final sample consisted of 47 first-level leaders from 43 different child and adult clinics (due to a change in leadership in three of the clinics, there are more leaders than clinics). Cohort 1 consisted of 14 clinics (16 leaders and 320 therapists), cohort 2 of 14 clinics (14 leaders and 235 therapists), and cohort 3 of 15 clinics (17 leaders and 249 therapists). Please see participant flow in the CONSORT diagram as Supplementary Material.

The LOCI training sessions (2 days at baseline and 1 day at 4, 8, and 12 month) were carried out face-to-face at the Norwegian Center for Violence and Traumatic Stress Studies (NKVTS). During these trainings, first-level leaders were introduced to general and strategic leadership principles and implementation climate. The leaders received feedback reports based on 360° assessments on their leadership and their clinics' implementation climate. Based on this, they developed individualized leadership development plans to progress toward improvements in leadership and climate which were updated based on new feedback reports every fourth month. The first-level leader had weekly coaching calls by phone with a LOCI trainer to strategize actions to take to achieve the goals defined in the leadership development plan. Once a month, the individual coaching calls were replaced with group coaching calls within each cohort.

The first organizational strategy meeting (OSMs), which involves first-level leaders and executive management, was conducted at each clinic following the first LOCI training sessions, whereas the following OSMs were conducted through digital platforms. Consistent with the LOCI strategy focus on alignment of first-level leader activities and organizational supports, data were shared with executives in each of the health trusts at every OSM. Climate development plans were co-created with health trust executives in order to better support first-level leaders in supporting their therapists in the implementation of EBPs for PTSD.

The LOCI strategy was administrated separately in the child and adult clinics by two teams at the NKVTS. The team for adult clinics consisted of two clinical psychologists and one PhD. The team for child clinics consisted of three clinical psychologists, one MA, and one PhD. Two of the five LOCI trainers in the child clinics were also responsible for training therapists in TF-CBT. Both teams were trained to deliver LOCI by the original LOCI developers. There were regular meetings between the Norwegian and US teams to discuss and review adaptations (such as context and design issues), translation of materials and measures, and fidelity to the LOCI protocol. LOCI's developer (GAA) participated at the first LOCI workshops and follow-up workshops with both teams, and attended and provided feedback on meetings with health trust executives. In addition, the Norwegian LOCI trainers had regular meetings to discuss the progress during the project period.

We collected data from all participating clinics throughout the study period, consistent with the stepped-wedge design. This was done using the Norwegian Centre for Research Data (NSD WebSurvey). There were 6 total data collection points (baseline in July 2018 and every four months until April 2020). The first two cohorts entered a sustainability phase at measurement times 5 and 6 respectively.

Measures

The employees completed questionnaires about their perception of their leader and implementation climate for their clinic. For all scales, questions were tailored to evidence-based screening and treatment of PTSD, referring to the screening instruments and treatment methods being implemented. The following scales were used (bootstrapping based on 1000 samples applies to all stated confidence intervals for Cronbach's alpha).

The Implementation Leadership Scale (ILS)

ILS is a 12-item questionnaire measuring leadership for EBP implementation (Aarons, Ehrhart, & Farahnak, 2014). It consists of four subscales: (1) proactive leadership, (2) knowledgeable leadership, (3) supportive leadership, and (4) perseverant leadership. It is scored from 0 (not at all) to 4 (to a very great extent). The total ILS score was created by computing the mean of the four subscales. Individuals who had data on half or more of the items in each subscale were included. The scale demonstrated excellent psychometric properties (12-items; α = 0.955, CI (95%) = 0.945–0.963).

The Multifactor Leadership Questionnaire (MLQ)

MLQ is a 36-item questionnaire which is built on the full-range leadership theory (39). It measures three leadership behaviors, including transformational, transactional, and non-leadership. Of these, the primary focus for this study was transformational leadership. Transformational leadership consists of four subscales (idealized influence, 8 items; inspirational motivation, 4 items; intellectual stimulation, 4 items; and individual consideration, 4 items). The other scales on the MLQ were also included in the analyses for comparison purposes. Transactional leadership (contingent reward, 4 items; active management-by-exception, 4 items; passive management-by-exception, 4 items) and non-leadership (laissez-faire, 4 items) consists of three and one subscales, respectively (40). Items responses range from 0 (not at all) to 4 (frequently, if not always). While the transformational leadership scale is psychometrically supported in the literature (41), the other scales covary differently both theoretically and empirically from standard psychometric representations (42, 43). We therefore created a total score for transformational leadership by calculating the mean scores across the four subscales, while analyzing the other subscales of transactional and non-leadership separately. Participants with data on two or more of the items in each subscale were included.

Psychometric properties for transformational leadership were excellent (20-items; α = 0.958, CI (95%, bootstrapping based on 1000 samples) = 0.948–0.965) while the subscales for Transactional Leadership all had good item reliability, specifically contingent reward (4-items; α = 0.846, CI (95%, bootstrapping based on 1000 samples) = 0.813–0.871), active management-by-exception (4-items; α = 0.881, CI (95%, bootstrapping based on 1000 samples) = 0.859–0.898), passive management-by-exception (4-items; α = 0.842, CI (95%, bootstrapping based on 1000 samples) = 0.812–0.868), and laissez-faire leadership (4-items; α = 0.867, CI (95%) = 0.838–0.892).

The Implementation Climate Scale (ICS)

The ICS is an 18-item questionnaire measuring a climate that supports EBP adoption and use in organizations (26). It includes six subscales: (1) focus on EBP, (2) educational support for EBP, (3) recognition for EBP, (4) rewards for EBP, (5) selection for EBP, and (6) selection for openness. It is scored from 0 (not at all) to 4 (to a very great extent). Participants with data on two or more of the items in each subscale were included, and the total ICS score was then calculated by computing a mean score of all subscales. The ICS showed very good psychometric properties (18-items; α = 0.894, CI (95%) = 0.873–0.910).

The Implementation Climate Measure (ICM)

To include a more global understanding of implementation climate, the ICM, a 6-item questionnaire measuring the general implementation climate in the organization, was also included (44). It includes three subscales measuring what is (1) expected, (2) supported, and (3) rewarded when implementing a new practice. The scale is scored from 0 (not at all) to 4 (often, if not always). As each subscale only contains two items, participants had to have data on all items to be included in the analyses. The ICM total scale score was calculated by the mean scores of all subscales. It showed excellent psychometric properties (6-items; α = 0.918, CI (95%) = 0.901–0.932).

Analyses

All data were exported from NSD WebSurvey to SPSS. The analyses were performed in R (45), using the nmle package (46) for the repeated measures. To assess the internal validity of ILS, MLQ, ICS and ICM, Cronbach's alpha was calculated using the cronbach.alpha function in the ltm package including a 95% confidence interval using bootstrapping with 1000 samples.

All analyses included data provided by therapists on their perception of general leadership, implementation leadership, and implementation climate. Data provided by leaders were excluded in the current study. In a repeated measures design, responses at the individual-level (i.e., therapists) and responses from individuals within the same clinic are likely to be correlated. To account for the dependency in the data, we used linear mixed effects models which allows for irregularly spaced measurement time periods (47), and missing data within measurements (48), with fixed effects representing different linear changes before and during the LOCI intervention, and random effects for differences between clinics, and differences in level and slope between therapists. The random structure was simplified when necessary for model stability, as recommended (49). The gap between the two linear fits, evaluated when LOCI began, represents the initial impact of LOCI training, where a positive value indicates improvement. Standardized versions of the initial impact, termed d, are computed by dividing by the square root of the combined variances for random effects in levels. If the post-LOCI slope is higher than the pre-LOCI slope, it indicates that the effects of LOCI training increase over time.

In order to examine possible differences between cohorts, training (i.e., received training in screening tools only or both screening tools and the EBPs for PTSD), and outpatient clinics (i.e., child or adult psychiatric care), we added categorical variables for cohorts, training, and outpatient clinics to the model in supplementary analyses. Separate parameters were included to test whether the LOCI training and the pre- and post- trajectories were different across child and adult clinics. Details on these supplementary analyses were only given if there was a significant interaction.

Results

The findings across the three leadership measures are consistent. Across the three cohorts and prior to LOCI enrollment there was a steady decrease in the therapist's perception of implementation leadership, transformational leadership, and a supportive implementation climate. When LOCI was introduced, there was a significant increase in leadership and climate scores over time across all outcomes (Table 3; Figs. 1–4). These findings are described in more detail below.

Table 3
The effect of LOCI based on mixed effects analyses

Effect	Estimate	95% CI		*p*
		LL	*UL*	
Implementation Leadership Scale (ILS)				
Value when LOCI starts				
Non-LOCI	2.05	1.89	2.21	< 0.001
LOCI	2.41	2.27	2.54	< 0.001
Difference LOCI-non-LOCI	0.36	0.25	0.47	< 0.001
Slope				
Non-LOCI	-0.121	-0.182	-0.060	< 0.001
LOCI	0.029	0.000	0.058	0.044
Difference LOCI- non-LOCI	0.151	0.084	0.217	< 0.001
Transformational Leadership (MLQ)				
Value when LOCI starts				
Non-LOCI	2.49	2.36	2.62	< 0.001
LOCI	2.63	2.52	2.74	< 0.001
Difference LOCI-control	0.14	0.05	0.22	0.001
Slope				
Non-LOCI	-0.104	-0.150	-0.057	< 0.001
LOCI	-0.015	-0.373	0.008	0.202
Difference LOCI- non-LOCI	0.089	0.039	0.140	< 0.001
Implementation Climate Scale (ICS)				
Value when LOCI starts				
Non-LOCI	1.82	1.72	1.91	< 0.001
LOCI	1.93	1.86	2.01	< 0.001
Difference LOCI- non-LOCI	0.12	0.04	0.20	0.004
Slope				
Non-LOCI	-0.062	-0.107	-0.016	0.008
LOCI	0.020	-0.001	0.041	0.062
Difference LOCI- non-LOCI	0.081	0.032	0.131	0.001
Implementation Climate Measure (ICM)				
Value when LOCI starts				
Non-LOCI	1.76	1.62	1.90	< 0.001
LOCI	1.98	1.88	2.09	< 0.001
Difference LOCI-non-LOCI	0.23	0.10	0.35	< 0.001
Slope				
Non-LOCI	-0.108	-0.179	-0.040	0.002
LOCI	0.012	-0.021	0.046	0.470
Difference LOCI - non-LOCI	0.120	0.043	0.198	0.002

Table 3 provides the main results of the analyses for the study. For each outcome of interest, the key implementation results are the difference between LOCI and non-LOCI sites at the first measurement point after LOCI for each cohort (i.e., the immediate difference), followed by the slope for that outcome for all available data points for LOCI versus non-LOCI (i.e., change after initial implementation). The figures display considerable variation across therapists using thin lines for all therapist scores in a spaghetti plot. Each figure represents a single implementation outcome (i.e., implementation leadership in Fig. 1, transformational leadership in Fig. 2, and implementation climate in Fig. 3). For each outcome, the estimates and comparison for the “value when LOCI starts” in Table 3 correspond to the intercept estimate at time 0 in the figures, and the slope estimates and comparisons correspond to the dark black lines for the non-LOCI and LOCI periods in the figures.

The effect of LOCI on implementation leadership (ILS)

As shown in Table 3 and Fig. 1, there was a positive initial effect of LOCI on implementation leadership relative to non-LOCI (difference = 0.36, $p < 0.001$, $d = 0.42$). This indicates that the therapists scored their leaders higher on implementation leadership following inclusion in LOCI. The slope for the pre-LOCI data was significant and negative, meaning that therapists rated implementation leadership steadily lowered their ratings over time before starting LOCI. The slope for the LOCI sites over time was significant and positive, meaning that therapists rated implementation leadership steadily increased their ratings after the initial increase at the start of training. These two slopes were significantly different from each other, further indicating that LOCI disrupted the early pattern of decreasing leadership ratings.

The effect of LOCI on transformational leadership (MLQ)

There was a positive initial effect of LOCI on transformational leadership relative to the non-LOCI (diff = 0.14, $p < 0.001$, $d = 0.19$) (Table 3; Fig. 2). This suggests that there was a significant increase in therapist´s rates on transformational leadership once the leaders initiated their participation in LOCI. The slope for the pre-LOCI data was significant and negative, meaning that therapists rated transformational leadership steadily lower over time before starting LOCI. The slope for the post-LOCI data was not significant, meaning that transformational leadership scores may have stayed consistent after the initial increase once LOCI was initiated. These two slopes were significantly different from each other. There was no significant change in therapists’ rates of transactional leadership (contingent reward, active or passive management-by-exception) or laissez-faire leadership.
The three-way interaction between outpatient clinics, time for inclusion in LOCI, and measure time for adult and child outpatient clinics was significant for transformational leadership ($p < .001$). Examination of the coefficients for the effect of LOCI on transformational leadership show that most of the effect was due to a change in the adult psychiatric clinics (Table 4). In particular, neither initial nor slope changes on transformational leadership were significant for child clinics, whereas both were significant and favored LOCI for the adult clinics.

Table 4
Mixed effects analysis on adult and child clinics (MLQ transformational leadership) and training in screening only compared to training in screening and EBP for PTSD (ICS)

Effect	Estimate	95% CI		*p*
		LL	*UL*	
Adult and child outpatient clinics – MLQ Transformational Leadership				
Child outpatient clinics				
Value when LOCI starts				
non-LOCI	2,67	2.47	2.86	< 0.001
LOCI	2.66	2.50	2.82	< 0.001
Difference LOCI- non-LOCI	-0.01	-0.14	0.12	0.928
Slope				
non-LOCI	0.001	-0.075	0.076	0.985
LOCI	-0.029	-0.006	0.004	0.089
Difference LOCI- non-LOCI	-0.029	-0.566	-0.012	0.479
Adult outpatient clinics				
Value when LOCI starts				
non-LOCI	2.38	2.19	2.56	< 0.001
LOCI	2.60	2.44	2.76	< 0.001
Difference LOCI-non-LOCI	0.22	0.12	0.33	< 0.001
Slope				
non-LOCI	-0.168	-0.227	-0.109	< 0.001
LOCI	-0.002	-0.033	0.029	0.903
Difference LOCI- non-LOCI	0.166	0.100	0.232	< 0.001
Training in screening only versus screening and treatment methods – ICS				
Training in evidence-based screening only				
Value when LOCI starts				
non-LOCI	1.91	1.79	2.03	< 0.001
LOCI	1.94	1.86	2.02	< 0.001
Difference LOCI- non-LOCI	0.027	-0.08	0.13	0.630
Slope				
non-LOCI	-0.001	-0.063	0.061	0.970
LOCI	0.017	-0.012	0.046	0.244
Difference LOCI- non-LOCI	0.018	-0.049	0.086	0.595
Training in evidence-based screening and treatment methods				
Value when LOCI starts				
non-LOCI	1.71	1.57	1.85	< 0,001
LOCI	1,94	1,84	2,03	< 0,001
Difference LOCI- non-LOCI	0.23	0.11	0.35	< 0,001
Slope				
non-LOCI	-0.132	-0.198	-0.065	< 0.001
LOCI	0.023	-0.008	0.053	0.143
Difference LOCI- non-LOCI	0.154	0.082	0.226	< 0.001

The effect of LOCI on implementation climate

There was an initial, significant positive effect of LOCI on implementation climate as measured by the Implementation Climate Scale (ICS) relative to the non-LOCI (diff = 0.36, $p < 0.001$, $d = 0.19$), with practitioners reporting higher scores on implementation climate after the introduction of LOCI (Table 2). The slope for the pre-LOCI data was significant and negative, meaning that ICS scores decreased over time before starting LOCI, and the slope for the post-LOCI data was not significant, meaning that ICS scores stayed relatively consistent after the initial increase once LOCI was initiated. These two slopes were significantly different from each other.

The results for the Implementation Climate Measure (ICM) were similar to the ICS results. There was an initial, significant positive effect of LOCI on implementation climate as measured by the ICM relative to the non-LOCI (diff = 0.12, $p = 0.004$, $d = 0.24$), which indicates that participants reported higher ICM scores after the introduction of LOCI (Table 2; Fig. 3). The slope for the pre-LOCI data was significant and negative, meaning that ICM scores decreased over time before starting LOCI, and the slope for the post-LOCI data was not significant. These two slopes were significantly different from each other.

Training in screening only versus training in screening and EBP for PTSD

There were no significant differences between individuals who had received training in screening only versus those who received training in screening and the EBPs for PTSD (TF-CBT, EMDR, CT-PTSD) on ILS, MLQ, or ICM (Table 3). However, there were significant differences between the two groups for ICS, suggesting that those who had received training in both screening and EBP for PTSD may have largely contributed to the effect of LOCI on the ICS ($p = 0.007$) (Table 4; Fig. 5).

Discussion

The translation of research into practice remains a challenge within mental health systems. Despite the documented importance of leaders in this respect, there is a lack of knowledge on the effectiveness of leadership development programs related to implementation of EBPs. Mental health care service practitioners experience high job demands and challenges such as burnout and turnover (7). To be able to successfully implement and sustain EBPs, clinic level and broader organizational leadership support is essential (25). The specific aim of this study was to investigate the effect of LOCI on implementation and transformational leadership, and implementation climate. Our results showed that the therapist-rated implementation and transformational leadership as well as implementation climate increased significantly after the leaders were introduced to the LOCI intervention. This increase was sustained throughout the project period, compared to non-LOCI conditions which demonstrated a steady decrease in scores before LOCI was introduced.

The current study demonstrated that following training in EBPs, the therapists' perception of implementation leadership and implementation climate decreased steadily over time. However, when the leaders received the LOCI intervention, the therapists' reports of implementation leadership and climate significantly increased. Thus, in line with our hypotheses, LOCI was beneficial for facilitating implementation leadership and a positive implementation climate. These findings also indicate that training of therapists in EBPs without having a clear implementation strategy and leadership support might have a detrimental effect, and that types of implementation supports provided by LOCI are necessary. If this is a generalizable finding it should have a large impact on how we implement EBPs and serve as a strong argument against dissemination through therapist-trainings only. Moreover, in order for the LOCI intervention to have long-term implications for mental health systems, the gains in leadership and climate must be maintained over time. These results indicate that the effects were maintained for the length of the project period (24 months).

There was a significant positive effect of LOCI on therapists reports of transformational leadership. However, subsequent analysis showed that the adult clinics may have mainly accounted for this effect. There was a larger drop in therapist-rated scores on transformational leadership in the adult clinics prior to engagement in LOCI, which means that there was more room for change. Also, therapists at the child clinics received approximately 40 cases of coaching as part of their TF-CBT training, whereas the adult therapists received 10 hours of coaching as part of their EMDR and CT-PTSD training. It might be that the different training models in the adult versus the child clinics accounted for the different patterns in the data before the introduction of LOCI at baseline as well as the different trajectories throughout the project period. For example, the therapists in the child clinics who received more coaching might have felt more connected with the other therapists (50), which could have affected their need for, and perception of, leadership support. Another explanation could be that the LOCI trainers in the adult clinics focused more on developing general leadership skills among the first-level leaders whereas the LOCI trainers in the child clinics focused more on the implementation of the PTSD treatment method as some of them also were the TF-CBT trainers.

There were no significant effects of LOCI on the transactional leadership dimensions or on non-leadership (laissez-faire leadership). This is not surprising since the focus of LOCI is to increase first-level leaders' transformational leadership as an additive to transactional leadership behaviors.

The group receiving training in both screening and EBPs for PTSD contributed to the effect of LOCI on implementation climate as measured by the ICS. The questionnaire targeted screening and EBPs for PTSD, and it might be that the therapists who were trained in screening only, perceived that the questions were not as relevant as for the practitioners that were also trained in the EBPs for PTSD. The results might also signal that those trained in both screening and EBPs for PTSD exhibit a larger need for implementation climate support. The scores on implementation climate were quite high at baseline among those trained in both screening and EBPs for PTSD, which might indicate enthusiasm over the new project. When therapists perceive implementation climate as good, it signals a shared belief that EBP is a true and lasting priority for the organization rather than a passing trend that can be ignored (28). Following the initial enthusiasm, it might be that those trained in both screening and EBPs for PTSD treatment experienced a drop in implementation climate over time until the LOCI intervention was introduced. On the other hand, among the therapists trained in screening only, the baseline scores were quite low. This might have been an expression of a wait-and-see attitude at the start of the project which was strengthened when they experienced that the implementation was more than a passing trend.

There was a significant interaction effect for implementation climate as measured by the ICS, but not the ICM, suggesting that mainly those who had received training in both screening and EBP for PTSD contributed to the effect of LOCI on the ICS. The ICS subscales are more specific in regard to implementation

climate dimensions (focus on EBP, educational support, recognition, rewards, selection for EBP, and selection for openness for EBP). ICM is a more global measure of implementation climate. Hence, it may be that LOCI had a positive effect on general implementation climate whereas only those trained in the EBPs experience a more positive implementation climate for specific dimensions.

This is the first study to investigate the effect of LOCI in a health care setting outside of USA. It is a strength that the study involved clinics all over Norway that implemented screening and EBP treatment. While the use of multiple assessment times strengthens methodological rigor, potentially increased respondent burden as a result may have impacted their responses. The next step would be to examine transformational and implementation leadership and implementation climate as implementation mechanisms between determinants and outcomes. Future studies should investigate whether LOCI, through improved implementation leadership and climate, contributes to increased use of EBPs—and ultimately improved client outcomes.

Conclusions

This study contributed novel knowledge about the effect of the LOCI intervention on key factors highlighted as important for successful implementation of EBPs – namely, leadership and climate. Implementation and transformational leadership and implementation climate were more positive evaluated after the leaders were introduced to the LOCI intervention, and this was sustained throughout the project period, whereas non-LOCI conditions demonstrated a steady decrease in therapist-rated scores before LOCI was introduced. LOCI seem like an appropriate implementation strategy for the first-level leaders to achieve better EBP implementation and sustainment within mental health care services.

Abbreviations

LOCI
Leadership and Organizational Change for Implementation
EBP
Evidence-based practices
PTSD
post-traumatic stress disorders
EMDR
Eye Movement and Desensitization Reprocessing
CT-PTSD
Cognitive Therapy for PTSD
TF-CBT
Trauma Focused Cognitive Behavioral Therapy
MLQ
The Multifactor Leadership Questionnaire
ILS
Implementation leadership scale
ICS/ICM
Implementation climate scale /implementation climate measure

Declarations

Ethics approval and consent to participate: Research approval from the Norwegian Centre for Research Data (NSD).

Consent for publication: Not applicable

Availability of data and material: The datasets will be available from the corresponding author on reasonable request.

Competing interests: GAA is an associate editor of Implementation Science. All decisions on this paper was made by another editor. GAA and MGE are developers of the implementation leadership model being tested. There are no other competing interests.

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Authors' contributions: AMSS and KME conceived and had the overall responsibility for all parts of the study. NB had a key role in preparing the data files and in data analysis, and contributed to the writing of the manuscript. NP, HB, and ME helped with planning the study, and preparing the data files for analysis. AB and RHB helped with planning and coordinating the study and data collection. TWL advised on and participated in the analysis. CHB contributed to the study design and randomization. MGE, MS, and GAA contributed to the conception of the study and the study design. All authors contributed in writing of the manuscript. All authors approved the final manuscript.

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Figures

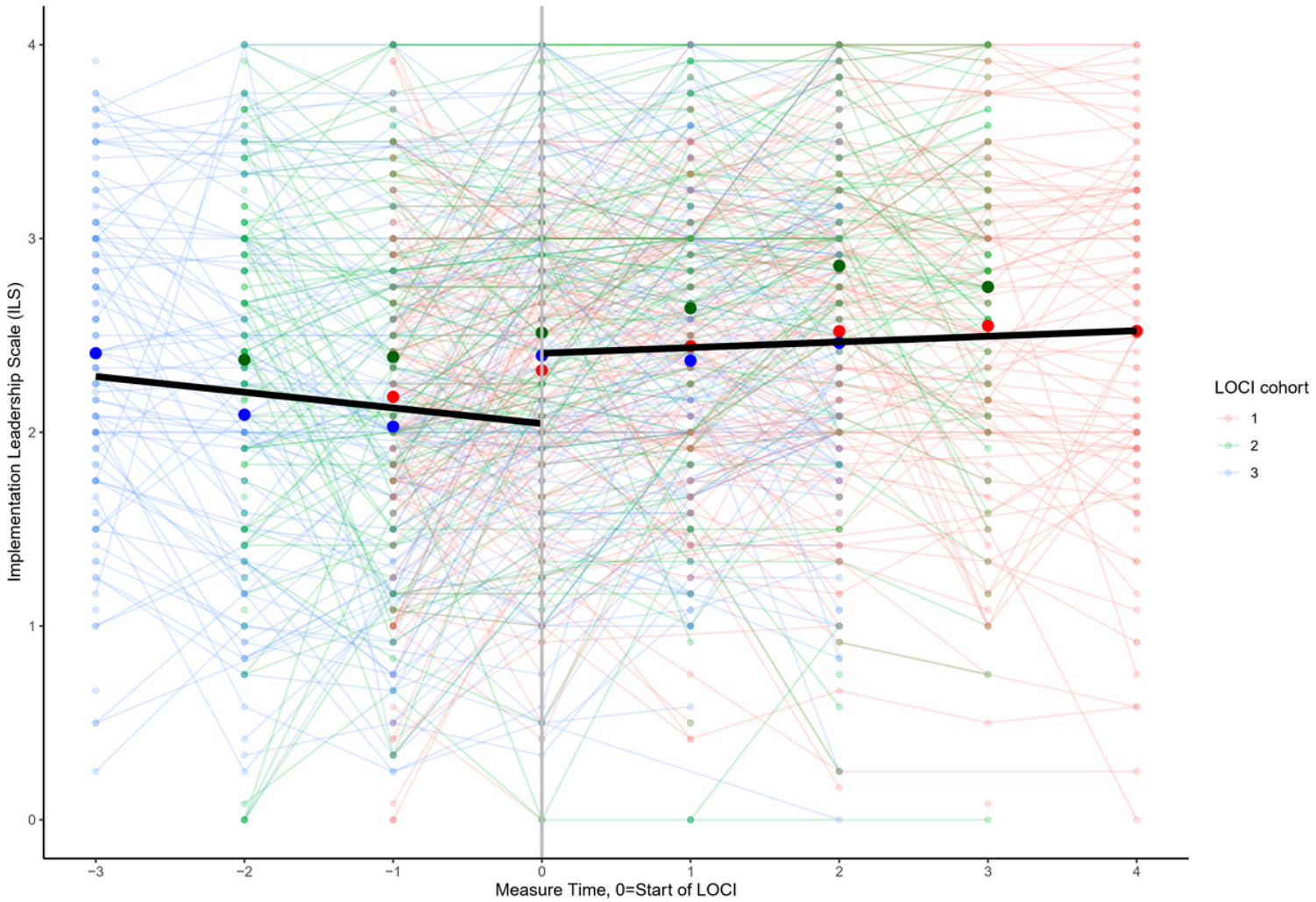

Figure 1

Staff-rated implementation leadership before and after the introduction of LOCI Note: Measure times -3 to -1 are the non-LOCI periods, while measure times 0 to 4 are the LOCI periods. Cohort 1 includes measure times -1 to 4, cohort 2 includes measure times -2 to 3, cohort 3 includes measure time -3 to 2. The black line represents the estimated slope in the non-LOCI and LOCI periods. The large dots show the trajectories for each cohort (respectively) over time.

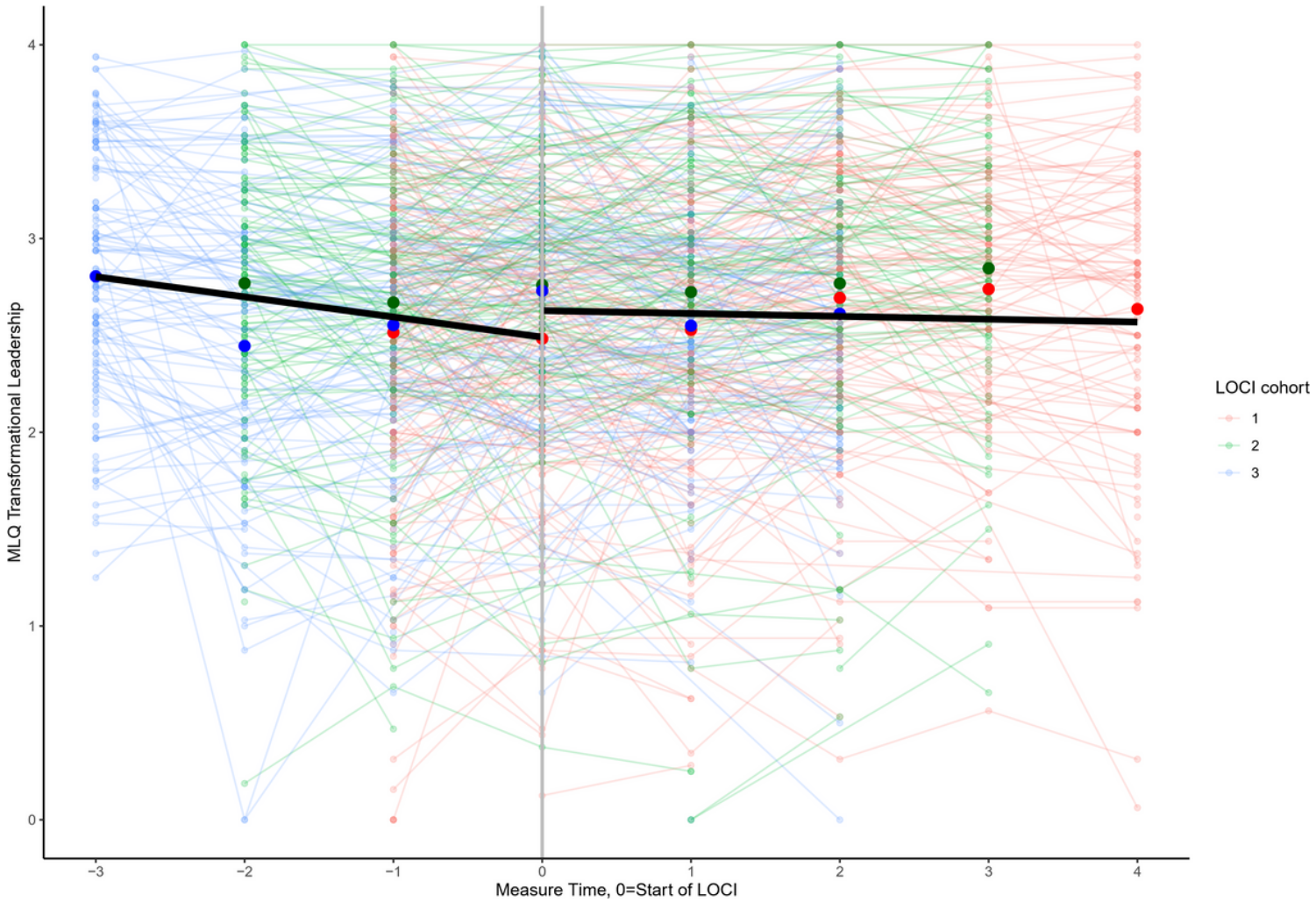

Figure 2

Staff-rated transformational leadership before and after the introduction of LOCI Note: Measure times -3 to -1 are the non-LOCI periods, while measure times 0 to 4 are the LOCI periods. Cohort 1 includes measure times -1 to 4, cohort 2 includes measure times -2 to 3, cohort 3 includes measure time -3 to 2. The black line represents the estimated slope in the non-LOCI and LOCI periods. The large dots show the trajectories for each cohort (respectively) over time.

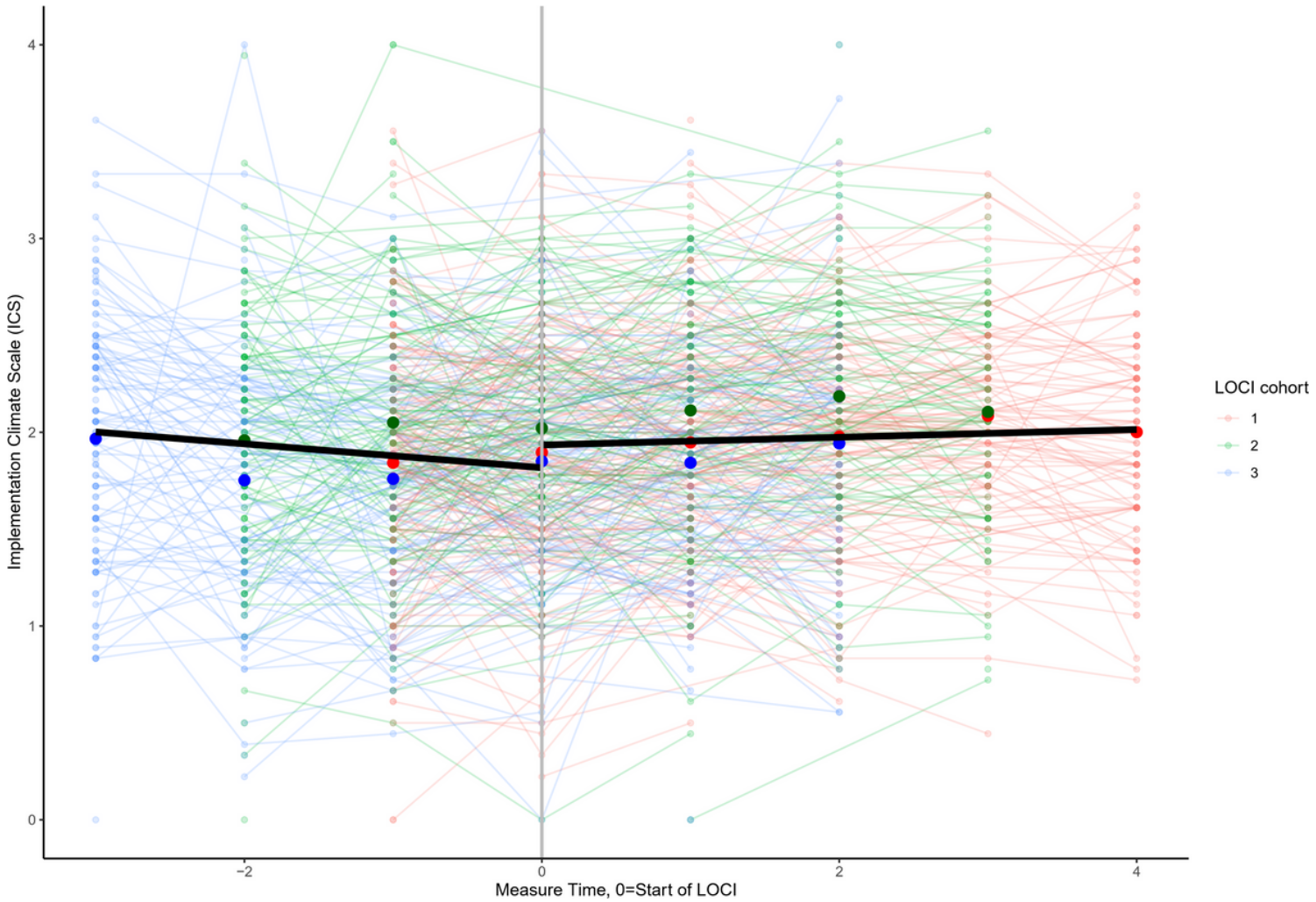

Figure 3

Staff-rated implementation climate (ICS) before and after LOCI Note: Measure times -3 to -1 are the non-LOCI periods, while measure times 0 to 4 are the LOCI periods. Cohort 1 includes measure times -1 to 4, cohort 2 includes measure times -2 to 3, cohort 3 includes measure time -3 to 2. The black line represents the estimated slope in the non-LOCI and LOCI periods. The large dots show the trajectories for each cohort (respectively) over time.

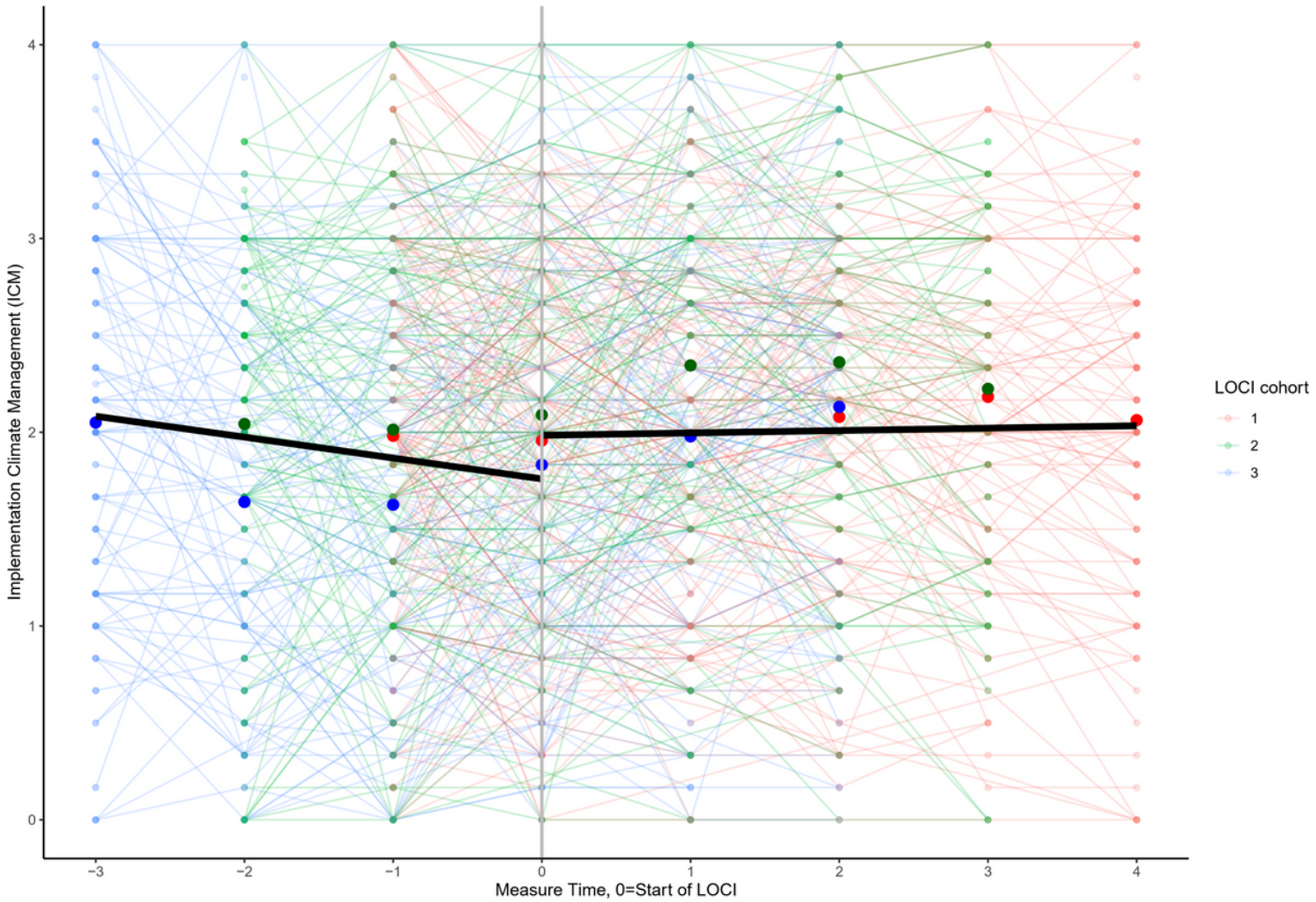

Figure 4

Staff-rated implementation climate (ICM) before and after LOCI Note: Measure times -3 to -1 are the non-LOCI periods, while measure times 0 to 4 are the LOCI periods. Cohort 1 includes measure times -1 to 4, cohort 2 includes measure times -2 to 3, cohort 3 includes measure time -3 to 2. The black line represents the estimated slope in the non-LOCI and LOCI periods. The large dots show the trajectories for each cohort (respectively) over time.

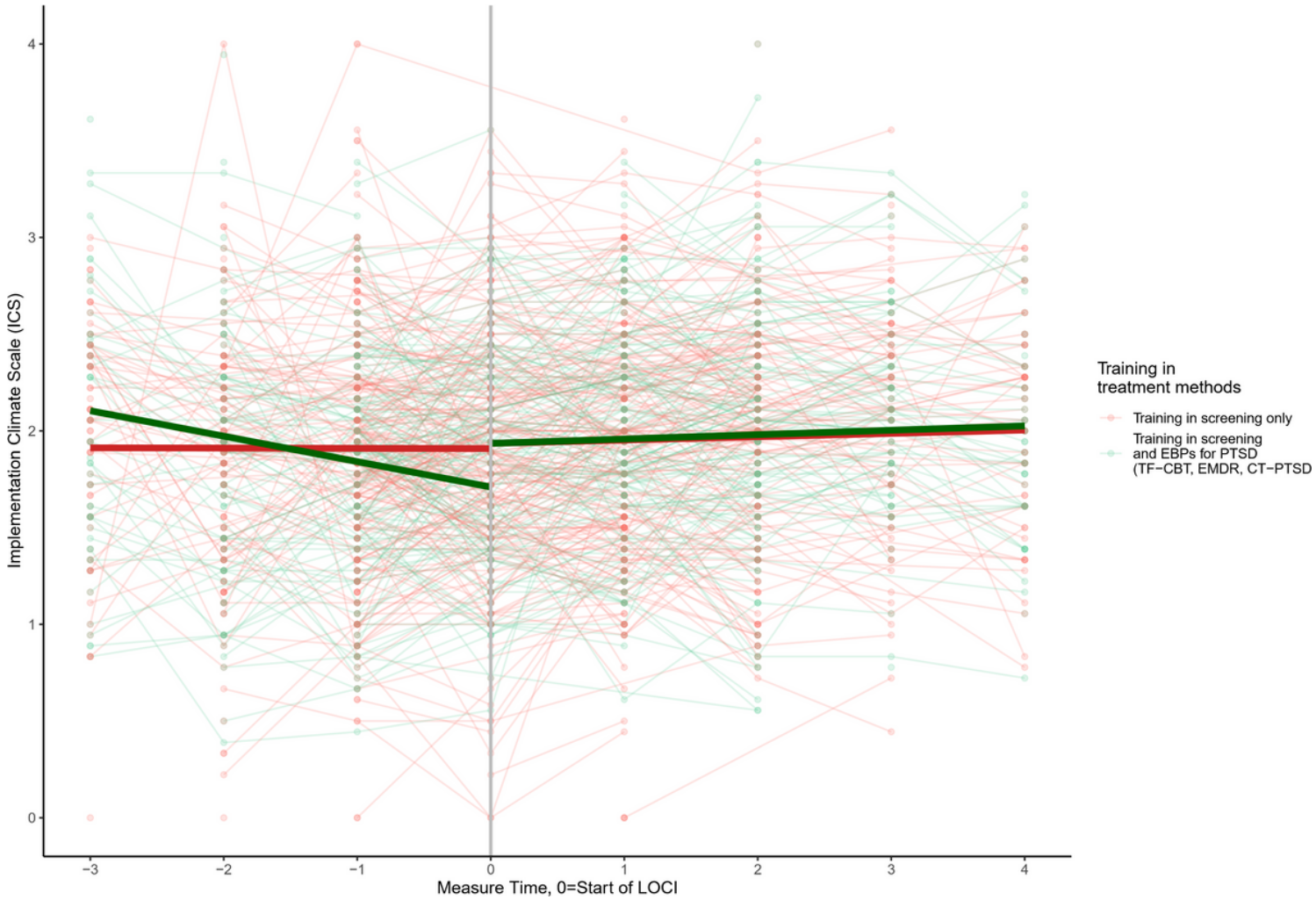

Figure 5

Staff-rated implementation climate among providers receiving training in screening only versus training in screening and EBP for PTSD treatment Note: Measure times -3 to -1 are the non-LOCI periods, while measure times 0 to 4 are the LOCI periods.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SupplementaryMaterial1CONSORT2010LOCIFlowDiagram.doc
- SupplementaryMaterial2CONSORT2010Checklist.doc