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iLead- Evaluation of a generic implementation leadership intervention: A mixed method pre-post intervention design

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iLead- Evaluation of a generic implementation leadership intervention

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Abstract

Objectives: The present study is an evaluation of the iLead intervention. We also investigate whether or not transfer of training can be supported by contextualizing the intervention (recruiting all line managers from one branch of the organization while focusing on one implementation case, as well as training senior management).

Design: A pre-post evaluation design was applied using mixed methods with process and effect surveys and interviews to measure the effects on three levels.

Setting: Healthcare managers from Stockholm's regional healthcare organization were invited to the training.

Participants: 52 line managers participated in the iLead intervention. Group 1 consisted of 21 managers from different organizations and with different implementation cases. Group 2, representing the contextualized group, consisted of 31 managers from the same organization, working on the same implementation case, where senior management also received training.

Intervention: iLead is an intervention where healthcare managers are trained in implementation leadership based on the full range leadership model (FRLM).

Primary outcome measures: Reactions, knowledge and implementation leadership are measured.

Results: Quantitative and qualitative analyses indicate that iLead was perceived to be of high quality and capable of increasing participants' knowledge. Mixed effects were found regarding changes in behaviors. The contextualization did not have a boosting effect on behavior change. Hence, group 2 did not increase their active implementation leadership in comparison to group 1.

Conclusion: iLead introduces a new approach to how implementation leadership can be trained when knowledge of effective leadership for implementations is combined with findings on the importance of environmental factors for the transfer of training. Even though

managers reported general positive effects, transfer was not facilitated through the contextualization of the intervention. There is a need to further develop approaches to help participants subsequently apply the learned skills in their work environment.

10 Keywords: contextualization, full-range leadership model, implementation leadership training, intervention, contextualization, organizational development

Strengths and limitations of this study

-The present study is based on a rigorous evaluation process of the iLead intervention using mixed methods, where the quantitative evaluation method is followed up by interviews to get a deep understanding of the effects.

-Effects of the iLead intervention are measured on different levels based on a thorough theory-based evaluation plan.

-Effects of the iLead intervention are, in addition to self-reports, measured through employee-ratings, where employees report on their managers' implementation leadership related to a current implementation.

- Multilevel modelling is applied to account for the nestedness of data, which is the case for longitudinal data.

-Drop out was more prominent in one intervention group and the response rate decreased over time.

Background

Implementing the ever-growing number of evidence-based methods into practice is an integral part of daily work in healthcare organizations. For implementation to be successful, leadership has been identified as a central factor [1–10]. However, many managers lack formal training in leadership and leading change, as they have often been promoted for their work as front-line providers [cf. 11]. In addition, existing studies on leadership during implementation have often lacked a theoretical underpinning [4–6,12], which prevents knowledge about how and why leadership is important for successful implementation. Accordingly, there is little research on how to train managers in leadership that facilitates the implementation process [e.g., 5]. Whereas there is some evidence for the effectiveness of training leaders in implementing evidence-based practice (e.g., EBP [13]) or specific evidence-based methods (e.g., preventing diabetic foot ulcers [14]), little is known about how to train generic implementation leadership, a skill that is needed when leaders are expected to lead multiple simultaneous implementations as part of their daily work. The present study is an evaluation of the "iLead" intervention that aims to train managers in generic implementation skills [15] answering to calls highlighting the need to provide and evaluate trainings directed at individuals in implementation roles and therefore focusing on implementation practice [16,17].

The iLead intervention

A large amount of leadership research has been based on the full-range leadership model (FRLM) [18,19] that describes both desired active leadership behaviors (i.e., transformational leadership and contingent reward) and undesired passive behaviors (i.e., management by exception and laissez faire). Active leadership has been related to positive organizational and employee outcomes [7,20–24] and fostering change [7,9,25]. Even though the FRLM has only

been used in a few studies that investigated implementation [e.g., 13], systematic reviews have identified leadership activities important for implementation that map well on the active leadership behaviors of the FRLM [5,6,10,26]. Based on this work, the FRLM was used in the iLead intervention [for the study protocol, see 15].

Fostering transfer through a supporting organizational context

Even though leadership development in general has been found to result in positive effects [7,27,28], it has been acknowledged that these often are limited to proximal outcomes such as reactions and knowledge [27,29]. Only 10% of training expenditure has been estimated to translate to behavioral change [30]. This highlights the transfer gap—the difficulty in translating knowledge and skills to the work setting [31]. Three primary factors influence the transfer of training: trainee characteristics, intervention design and delivery, as well as the post-training work environment [32]. Trainee characteristics include personality, the motivation to participate and existing skills, whereas intervention design and delivery defines the objectives of the training and the applied pedagogical methods that are used to bring about skills. The post-training work environment refers to the organizational context of participants, such as social support, transfer climate and the opportunity to perform and follow up of the new skills. Even though trainee characteristics could be used for the selection of participants, this is often not possible in practice; hence, the intervention design and the post-training work environment are factors that can be proactively tackled by interventionists to leverage transfer [cf. 33]. Therefore, in designing the iLead intervention, pedagogical tools to facilitating transfer were focused on (i.e., how the iLead workshops were brought about) (see upper part of table 1). Moreover, a feature that sets iLead apart from other interventions is its effort to further foster transfer by incorporating a contextualized intervention group to also manipulate the training work environment. Here senior management and all line managers from one

organizational branch participated in the training and worked on the same implementation case (see lower part of table 1). Involving senior management is important as they not only allocate resources and have the power to restructure processes and structures to make the implementation work [34], they also generate and help maintain managers' and employees' commitment [35] and compliance with an intervention [36].

_____Table 1 about here_____

Table 1. Intervention design and post training work environment factors to facilitate transfer of training and the operationalization in the iLead intervention

	Facilitators for transfer of training	**Elements in the iLead intervention**	**Intervention group**
Intervention design	Behavioral modeling	Role play, planning their actions and practicing between workshops	1 & 2
	Error management	Role play, practicing between workshops and revising the action plan, one workshop on handling resistance and continuous problem solving	1 & 2
	Realistic training environment	Working on an ongoing implementation, practicing between workshops, examples from health care in the workshops	1 & 2
Training work	Peer and supervisor support	All line managers from one organization, in addition to a senior manager intervention	2

	Transfer climate	Interventions on different levels in the organization to create a shared mental model about implementation	2
	Opportunity to perform	One common implementation and the support of senior management to create alignment and direction	2
	Follow up structure	One common implementation and the support of senior management to create alignment and direction	2
env	in		

The present study

The overall aim of this study is to examine the primary outcomes of iLead, an intervention based on the FRLM [18,19] to train healthcare managers' generic implementation leadership. Based on Kirkpatrick's four-level evaluation model [37], four questions are addressed with a mixed-method evaluation:

1. How do managers perceive iLead?
2. Does iLead increase managers' knowledge related to implementation leadership?
3. Does iLead increase managers' skills in leading a current implementation?

Furthermore, we investigate under which conditions the iLead intervention has greater impact by studying the contextualization of the intervention. Thus, two intervention conditions were compared: an individualized group (group 1) and a contextualized group (group 2). We expect no difference between the intervention groups regarding to their reactions and learning because both groups were exposed to the same intervention content and pedagogy. In contrast, we expect that contextualization (group 2) will facilitate the transfer of training resulting in the fourth question:

4. Does iLead lead to in a larger change of the behavioral outcome, i.e. generic implementation leadership, in group 2?

Method

A mixed-methods pre-post evaluation approach was applied with a two-armed, non-randomized intervention design in which managers—based on their organizational belonging—were assigned to one of the two intervention groups.

Setting and participants in the intervention

Healthcare managers from Stockholm's regional healthcare organization were invited to participate in an implementation leadership training. More detailed information about the recruitment process can be found in the study protocol [15]. In total, 52 managers participated (see table 2). Group 1 consisted of 21 managers from different branches of the healthcare organization who work with different implementation cases during the intervention. Group 2 consisted of 31 managers from one division of the regional healthcare organization, where senior management made participation in the training mandatory. With some exceptions, line managers worked with the same implementation case.

____Table 2 about here____

Table 2. Descriptive statistics of managers in the two intervention groups

	Intervention group 1 (individualized group)	Intervention group 2 (contextualized group)
Number of participants	21	31
Total attrition	11	4

Dropout		
– Before the start of the intervention	3	2
– After WS1/2	3	1
– After WS3	1	1
– After WS4	1	-
Women	92.3%	96%
Age	50 (9.1)	50.8 (8.3)
University education	73.3%	81.3%
Years being a manager	3.3 (2.09)	4.4 (3.9)
Number of employees	25.15 (12.70)	21.83 (7.78)

Notes: means and standard deviations are presented for age, years as managers and number of employees.

The two groups of managers had similar demographic characteristics, which are representative of employees in the Swedish healthcare sector [38] (see table 2). Attrition was greater for group 1 (for details and time of drop out see table 2). On average, managers from group 1 participated in three out of the four training occasions (SD=.84), whereas managers from group 2 participated on 3.5 occasions (SD=.79).

Intervention

The iLead intervention consists of five half-day workshops, which were provided at four occasions. The intervention content was the same for intervention groups 1 and 2. More detailed information about the development and content of iLead can be found in the study protocol [15].

Patient and public involvement

Important stakeholders (national experts, senior and line managers) were involved in co-creating the intervention to ensure a good fit between iLead and the healthcare context and the participants' needs [39]. Patient's involvement was not applicable in this study.

Data sources for the evaluation

A sequential exploratory design was used [40]. Quantitative surveys were conducted prior and twice after the intervention followed with qualitative interviews to enhance our understanding of the training impact. Shorter process evaluation surveys were also conducted after each individual workshop. To strengthen the research design, the participating managers, as well as their employees, were included in the data collection.

Table 3 shows response rates for the effect and process evaluations. Response rates decreased over time, which is common in longitudinal studies [41].

____Table 3 about here____

Table 3. Response rates for managers and employees

	Process evaluation (manager data)				Effect evaluation (employee data)		
	WS1/2	WS3	WS4	WS5	Pre-test	Post-test 1	Post-test 2
Group 1	15/18 (83.3%)	10/15 (66.6%)	8/14 (57.1%)	10/10 (100%)	252/477 (52.8%)	160/368 (43.4%)	132/268 (49.2%)
Group 2	26/29 (89.5%)	23/28 (82.1%)	22/27 (81.4%)	22/27 (81.4%)	432/607 (71.1%)	313/562 (55.6%)	292/544 (53.6%)

Nine individual semi-structured interviews were conducted by a researcher who was not involved in the intervention. The interview guide was developed based on Kirkpatrick's evaluation model and Baldwin and Ford's transfer of training model [32,37] (for the interview guide, see appendix). Interviews, which lasted for approximately one hour, took place at the respondents' work places and were recorded and transcribed verbatim by an external transcription service.

Measures in the process evaluation and pre-post effect evaluation surveys

Measurements are described in Table 4.

___Table 4 about here___

Table 4. Constructs in the process evaluation and pre and post intervention surveys

Research question	Construct	Content	No. of items	Response alternatives	Reference	Time of measurement	Cronbach's alpha
			Process evaluation (manager data)				
1	Appraisal of the intervention as a whole	Complexity, relevance, novelty, valence involvement	10	ten-point continuum for each adjective pair	[42]	WS5	.81 .68 .84 .60 .29
2	Knowledge about implementation and		6	1 (strongly disagree) - 10 (strongly	specially constructed to match	WS1/2, WS3,	.90 .97

1

	implementation leadership			agree)	the iLead intervention	WS4, WS5	.93 .97
			Pre and post intervention surveys (employee data)				
3	Changes in implementation and leadership	Extent of perceived changes in the implementation of the new method as well in the manager's leadership during the last six months	2	1 (big impairment) - 5 (no change) to 10 (great improvement)	[43,44]	T2 T3	.79 .74
4	Active implementation leadership	Leadership behaviors in line with FRLM related to the implementation	13	1 (strongly disagree)- 5 (strongly agree)	[45]	T2 T3	.95 .96

Notes: WS= workshop, T2= post measure 1, T3= post measure 2

Analyses

Multilevel modeling was used to analyze data based on three or more repeated measurements to account for the hierarchical nature of the data [46]. Two-level models with the repeated measure at the first level and the individual person at the second level—the individual employee at the first level and the group belongingness at the second level, respectively—were constructed. Nested models were compared by using full maximum-likelihood estimation [46]. Time was centered on the baseline, respectively WS1/2, whereas the group remained uncentered (0=intervention group 1, 1=intervention group 2). The multi-level models were run in Mplus 7.2, whereas all other analyses were conducted in SPSS 24.

Interviews were analyzed using thematic data analysis [47]. A semantic approach was used, (i.e., the explicit meaning of the data was analyzed). Patterns in the narrative material that captured something important in relation to the above-outlined evaluation models were selected [32,37]. Next, the themes were reviewed by the research team. A few themes were revised or excluded because they overlapped with other themes or were less prevalent (raised by less than three respondents).

Results

Reactions to the intervention

Participants were satisfied (ratings over 7) with the training's complexity, relevance, valence, their involvement and the novelty of the content. No group differences were found (see table 5), which is in line with our expectations. The quantitative results were strengthened by interview data (for quotes, see the bottom of table 5). In the analysis two themes emerged.

First, managers emphasized that they were able to work hands-on with their implementation cases, which differed from other trainings they had attended (Quote 1). Moreover, they highlighted the usefulness of the action plan guiding their implementation work during the iLead intervention, which made their intuitive knowledge of the implementation process more explicit (Quote 2) and helped them clarify the implementation for employees. Secondly, the use of role play was perceived to be influential on the managers' development and understanding (Quote 3).

___ Table 5 about here___

Table 5. Reactions to the intervention and related quotes

	Complexity	Relevance	Valence	Involvement	Novelty
Group 1	9.15	9.35	9.15	8.85	7.85
Group 2	8.52	9.06	8.63	8.56	7.09
Difference	$t_{(30)}$=.99	$t_{(30)}$=.58	$t_{(30)}$=.90	$t_{(30)}$=.55	$t_{(30)}$=1.63
Notes: independent t-test did not reveal significant differences between the two groups					
	Interview quotes				
Quote 1	ID7: What has been the best, and most beneficial, for me was to be very concrete. Often when participating in various kinds of education programs, you get a theoretical top-up in some way, and then there is usually another step where you as a participant need to think about how to work with this in your practice alone. It is pretty easy to get stuck in this process and fail to follow through... //				
Quote 2	ID 9: …when I got to see this training, I felt that I was pretty good at implementation, simply out of experience. I have learned through experience.				

	But what I haven't done is a structured implementation action plan, previously I had gone through the steps only in my head. This structured process plan, I feel…will give me an enormous strength in the future.
Quote 3	ID2: Yes, I really appreciated those exercises, both when we were to give a talk [about our implementation case] and catch the others' interest, and then this exercise where there was a challenge...where there was a group that had been told to have different opinions [about the implementation case] and then a manager tried to handle that. // I think that was very valuable. Role plays and when you get to practice with each other, that helped me a lot.

Improvements in implementation leadership knowledge

Managers from both intervention groups reported an increase in knowledge about implementation and how to lead this process (see Table 6), which is in line with our expectations. In the interviews, managers expressed increased knowledge concerning implementation leadership as a generic skill, the structure and the iterative nature of the implementation process (see Table 6, Quote 4 & 5) and the possibility to lead an implementation decoupled from knowledge about the specific content of the implementation (Quote 6).

__Table 6 about here ___

Table 6. Multilevel models predicting change in knowledge and related quotes

	Knowledge		
	Model 1	Model 2	Model 3
Intercept	6.92*	5.97*	6.37*

Time		.41*	.42*
Group			-.62
σ^2_{within}	1,39*	1,10*	1,10*
σ^2_{u0}	1,12*	1,20*	1,11*
-2*log(lh)	497.62	474.3	471.8
df	3	4	5
Δ-$_{2*log(lh)}$		23.3*	2,5
Δ_{df}		1	1

Note: Table entries represent unstandardized parameter estimates. Individual level: N =128-140; group level: N =42. Time is centered at WS1/2, intervention group is coded 0=intervention group 1 and 1=intervention group 2, *p<.05.

Interview quotes	
Quote 4	ID9: ... I have become more conscious and more structured concerning what I need to think about when working through the different steps [of the implementation], and also the clarification of what behavior it is that I want to change.
Quote 5	ID1: It is not a failure that it didn't go well… //…like, okay, we tried something, oh well—let's try again, and in this way you can proceed. So, it [the action plan for the implementation] is not finished when you launch it.
Quote 6	ID7: //…the *leading* aspect is somehow something you can learn; to implement something new without having to have deep knowledge of the particular [implementation case]…then I can feel more confident in managing restructurings. //…previously when I have been manager and implemented quality registries…//…I think I lost myself in the content [of the implementation] in some way…//

Improvements in implementation leadership behavior

When reviewing the last six months, employees experienced an improvement in implementation and their manager's leadership practices. No difference was found between the intervention groups (see Table 7, left side). Active implementation leadership at T2 did not differ between groups nor did group 2 have a steeper increase in implementation leadership between T2 and T3 (see Table 7, right side).

__Table 7 about here____

Table 7. Multilevel Estimates for Models predicting implementation leadership (employee ratings)

	CP T2		CP T3		AIL T2		AIL T3	
	Model 1	Model 2	Model 1	Model 2	Model 1	Model 2	Model 1	Model 2
Intercept	6.10*	.6.36*	5.93*	3.36*	3.76*	3.70*	3.64*	.97*
CP[a]/AIL[b] T2	-		-	.42*[a]	-		-	.73*[b]
Group		-.42		.06		.10		-.12
σ^2_{within}	2.63*	2.64*	2.65*	2.33	.65*	.65.23*	.62*	.35*
σ^2_{u0}	.09	.04	.51*	.39	.24*		.60*	.18*
-2*log(lh)	660.67	658.3	728.4	645.6	436.74	426.5	486.46	336.0
df	3	4	3	5	3	4	3	5
Δ-$_{2*log(lh)}$		2.4		82.8*		.2		150.5*
Δ_{df}		1		2		1		2

Note: unstandardized coefficients, CP= Changes in leadership procedures, AIL= Active implementation leadership, *p<.05.

To sum up, employees experienced a positive change in both the implementation process and their manager's leadership practices, but no difference between groups could be found regarding an increase in active implementation leadership. Interviews provided a deeper insight in what participants perceived as particularly valuable and provide examples on altered ways of leading implementations. However, the boosting effect of the contextualization, which should facilitate a transfer of training for group 2, was absent. It became clear that varying attitudes toward the common implementation case (Table 8, quotes 7), the timing of the iLead intervention in relation to a concurrent major organizational change (Table 8, quotes 8) and a perceived lack of support from senior management and peers (Table 8, quotes 9) may have mitigated the impact that the contextualization had on the outcomes.

__Table 8 about here____

Table 8. Quotes related to the contextualization

	Interview quotes
Quote 7	ID11: It was in the midst of this reorganization when managers were dealing with crying employees who were going to be transferred and so on. And then one was asked to focus on implementing the new [common] program. There must have been a lot of other cases that we could have implemented that would have been more appropriate to implement at this moment in time…
Quote 8	Id 7: I think that it was unfortunate that we were in the midst of the reorganization while the training program was simultaneously running. I think that it was very interesting to participate in the training and that it is very important for all of us to do this. However, I think that employees may have

	been in a slightly different mindset as a result of the reorganization, and were more concerned about how things would change in their daily job (e.g., who they were going to collaborate with later that year, what unit they would belong to, etc.). Change happens, but on this scale – once in a decade, maybe, so it is not very often..
Quote 9	ID14: I feel that they [the senior management] have not been able to fully handle the situation [with supporting line managers as part of the training], which I believe—yet again—is the result of the timing. If it was not for the reorganization that was occurring in the midst of everything, then I think the senior management would have focused more on supporting us.

Discussion

This study focuses on the outcomes of iLead, an intervention training healthcare managers' generic implementation leadership. Results showed that managers perceived the content, as well as the pedagogy of the intervention, to be relevant and of high quality. Moreover, they perceived that their knowledge about implementation leadership had increased throughout the intervention. However, behavioral effects were mixed. The employee transition ratings on the progress regarding the implementation and the leading of it indicated an improvement, which also the interviews showed, where managers talk about altered ways of thinking about implementation and how to lead it. Despite our attempt to facilitate transfer by contextualizing iLead, by offering interventions to both line and senior managers from one organization and working on the same implementation case, no difference between the two intervention groups in implementation leadership or its increase over time could be found. According to previous literature transfer of training may be facilitated when there is a common understanding about implementation, alignment across hierarchical levels and social

support among colleagues and from senior managers [34–36,48]. The interviews with managers provided insight into why the contextualization of iLead might not have resulted in the anticipated boosting effect. First, managers' attitudes regarding the common implementation case were mixed. Some embraced it, others were opposed to it, and that had been so for a long time: The implementation had been ongoing for some years with several setbacks. The fact that senior management made it mandatory to focus on this specific implementation case in the iLead intervention caused frustration. Thus, it seems likely that the readiness for the implementation case differed between the intervention groups; possibly managers in group 1, who were free to choose their implementation case, experienced higher readiness for their implementation case than managers from group 2, who were expected to work with a particular implementation. This may have decreased the managers' ability to make the most out of the exercises in the iLead intervention, which resulted in reoccurring discussions about the feasibility of the implementation case in the workshops for group 2. This presents the challenge of separating attitudes and experiences of the leadership training and its contextualization from the attitudes and experiences of the implementation case. Nevertheless, it also points toward the importance of the fit between perceived needs of the organization and the evidence-based practice that is implemented [e.g., 2,49,50]. Hence, even when the focus of an intervention is on implementation leadership such as iLead, rather than a specific evidence-based practice [e.g., 13,14], it may still be necessary to offer support to the organizations and participating managers to ensure the feasibility of the implementation case before accepting participants for this kind of intervention.

Second, major organizational change concurrently occurred with the intervention. In group 2, managers described conflicting focus, both for themselves and for employees, who in some cases were to change teams. However, managers from group 1 also experienced organizational changes, yet they reacted differently. They mentioned the changes, but did not

pay as much attention to them, nor did they describe them as a major hindrance in participating in the intervention and conducting the implementation. However, in group 1, attrition was higher, which might indicate a conflicting focus. The impact of line managers' attitudes toward the common implementation and the timing of the iLead intervention and organizational change in group 2 may be elucidated by research on mental models [34]. Mental models concern underlying psychological beliefs, which affect participants' reactions and behaviors. Even though the quantitative evaluation of the iLead intervention revealed positive reactions, the interviews indicated mixed—in some cases, critical—beliefs regarding the implementation case and the timing of the organizational change. For an intervention and its implementation to be effective, the participants should believe that there is a problem that the intervention is suitable to address, which motivates them to participate in the intervention activities [51]. Whereas no difference in intrinsic motivation to participate in iLead was found between the two intervention groups, extrinsic motivation was higher in group 2 (analysis can be obtained from the authors). This is possibly a consequence of senior management making the training mandatory for line managers. Third, when whole organizations undergo an intervention, the group dynamics and existing organizational culture is brought into the intervention. Consequently, skeptical or conflicting mental models about the intervention can receive more attention and need to be addressed. For example, for group 2, workshop leaders had to spend more time on managing issues that originated from the organizational context (e.g., the skeptical attitude toward the common implementation case). In addition, in the contextualized group senior management took part in an intervention of their own, aiming to support line managers. However, this support was only partly perceived by line managers. Even though senior management themselves developed through this intervention [for more information, see 52], it did not result in a dialog between line and senior management to create alignment between organizational levels. The timing of the senior management

intervention in relation to line managers' intervention may have been suboptimal. Important discussions that would have had the potential to facilitate the implementation process, if issued earlier, emerged among senior management during their intervention. More preparation time to define the implementation case and senior management's role in supporting line managers in their implementation process might have been beneficial and should be adjusted in future multi-level interventions [52]. In sum, although contextualization may theoretically have several benefits, such as providing social support, direction and alignment of the implementation to boost transfer, this study highlights several impeding factors that may have outbalanced these potentially beneficial effects. A more thorough organizational analysis prior to the intervention to identify barriers for the intervention and the implementation case is recommended. Hence, the general implementation and group climate, the history with the implementation case and the structure and opportunities to perform in line with the implementation should be investigated, along with participants' capacity and readiness for this implementation. Based on this analysis, preparatory workshops for the actual intervention should be provided. Even though the content of the parallel line manager and senior management interventions should be retained, more elements fostering the dialog between the two hierarchical levels should be included [52].

Strengths and limitations

This study has several strengths that should be highlighted. First, iLead is a generic intervention that is theory driven and has been developed involving relevant stakeholders (e.g., line and senior management). It is based on the FRLM, which mirrors relevant leadership behaviors that were also previously identified in implementation research [5–10,26]. As it has been highlighted that general active leadership is not sufficient to reach specific results (e.g., a successful implementation) [20,53], iLead focuses on active

implementation leadership. Second, to evaluate iLead, a sophisticated longitudinal multisource design has been applied using both quantitative and qualitative data, which made it possible to capture the intervention context and ongoing process to understand the effects of iLead. Third, evaluation was facilitated by the iLead scale [54], capturing implementation leadership of the specific implementation case. The scale was specifically developed for this purpose, as it has been highlighted that the utilized evaluation criterion needs to be aligned with the intervention content [55]. The iLead scale can also be a useful tool in practice to provide mangers with feedback regarding their implementation leadership.

The current study has also some shortcomings that must be acknowledged. First, the recruitment processes for the intervention and assignment to the two intervention groups might have introduced a systematic bias. Randomization of managers was not possible and we cannot exclude that intervention groups differed systematically. Moreover, drop out varied between the groups, which might have affected the generalizability of results, particularly for group 1. Furthermore, the lack of randomization makes it impossible to separate effects of time from effects of the intervention, hence, an evaluation framework and multiple data sources were used to mitigate the risk of erroneous conclusions. Second, some outcomes (reactions and learning) relied on self-reports, which can be biased through common method bias [56,57]. Third, to investigate behavior change as an effect of the iLead intervention transition rating questions where used. Transition ratings are ascribed to overestimate effect sizes [58] as well as being influenced by the present state bias [59,60]. These biases could however not be found in a recent study comparing different ways of assessing change [61]. A traditional pre-post evaluation measurement was not feasible for several reasons. First, the iLead scale [45] could only be administered at the two follow up measurements because managers were still undecided regarding their implementation case when the baseline measurement was conducted pre intervention. Moreover, a comparisons of overall mean

changes pre-post intervention might not to be feasible in iLead, where each manager's work took its starting point in her/his specific stage of her/his specific implementation case to assure the perceived usability of the intervention. Even in the contextualized intervention group, where the same implementation case was a focus, local conditions varied and led to different time plans. Hence, timely aligned of measurement with managers' individual change processes [62] is challenging with individualized interventions when the implementation process does not follow the time frame of the intervention; that is, when managers differ in their implementation progress and, therefore, vary in their ability to show implementation leadership. In addition, managers set individual leadership goals based on their strengths, weaknesses and work group needs. While probably beneficial for the individual participant, tailoring the intervention to the participants created a large variation of goals and pace in the implementation. Fourth, healthcare organizations are fast-moving entities with high turnover [63], resulting in changes in the work unit composition across measurement times manifesting in different sample sizes for the analyses. Only a smaller group could be followed across all three time points. In addition, whereas iLead focused on active implementation leadership, recent research shows that destructive leadership has detrimental effects [20,64]; hence, including how to decrease passive leadership in leadership trainings is another avenue for future research.

Conclusions

This study shows that a generic implementation leadership training that is based on the FRLM may lead to positive outcomes in participating line managers' reactions and implementation knowledge. However, it also shows how hard it is to achieve transfer from training to behavioral change. Efforts to support transfer through contextualization was not successful. Potential explanations are offered by interview data, which suggest a counter effect of

impeding organizational factors. Hence, contextualization may not be sufficient to counterbalance such factors, calling for a thorough organizational analysis to identify hindering factors for the implementation beforehand.

Abbreviations

FRLM - full range leadership model

EBP - evidence-based practice

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Ethical approval and consent

All procedures were approved by the regional research ethics committees in Stockholm, Sweden (ref no. 2015/857-31/5). Written informed consent was obtained for all study participants.

Patient consent Not required.

Availability of data and materials

The analyzed dataset used for this study is available from Dr. Anne Richter (anne.richter@ki.se) on reasonable request.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

Authors' contribution

AR: Study conception and design, Acquisition of data, Analysis and interpretation of data, Drafting of manuscript, Critical revision

CL: Analysis and interpretation of data, Drafting of manuscript, Critical revision

HH: Study conception and design, Acquisition of data, Analysis and interpretation of data, Drafting of manuscript, Critical revision

UVTS: Study conception and design, Acquisition of data, Analysis and interpretation of data, Drafting of manuscript, Critical revision

RL: Interpretation of Data, Drafting of manuscript, Critical revision

RM: Analysis and interpretation of data, Drafting of manuscript, Critical revision

TH: Interpretation of Data, Critical revision

UES: Acquisition of qualitative data, Analysis and interpretation of qualitative data

All authors approved the final version.

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Appendix 1. Interview guide

Introduction:

Can you describe your role as a manager?

Transfer of knowledge to practice:

-What have you learnt from the training? How have you used what you have learnt in the training?

-Have you learnt something during the training that you are keen to use related to your leadership? Something that stands out as particularly important?

-Which parts of the training did you perceive to good and where there parts that were missing?

-Have you had the chance to use what you have learnt during the training? Can you provide examples?

-Can you recall a work situation when it worked well to use what you learnt in the training? What do you think was the reason for why it went well?

-Do you think there will be more of these situations where you will be able to use the things you learnt in the training?

-Where there situations where you used something from the training in a different way? Did that result in the desired outcome? And why?

-Have you experience difficulties in using what you have learnt in the training in your practice?

-Have you experienced conflicts between the training and your workplace/practice when you have tried to use the new leadership behaviors?

-Have you experienced something in you or your situation that can make it more difficult to use these new leadership behaviors?

-Can you recall a work situation when it did not work well to use what you have learnt in the training? What do you think was the reason for this?

-What could facilitate that you can use the knowledge from the training? Factors in you or your workplace?

-How much effort have you invested to try using what you have learnt in the training?

-Did you receive the support that you would have needed to use what you learnt in the training? What and which aspects have been supporting?

-If not, which support would you have needed to be able to use what you have learnt in the training at your workplace?

-Do you experience that the training has change your or others way of thinking about the implementation? Can you give concrete examples?

-Do you experience that the training has changed your or others behavior at your workplace? Can you give concrete examples?

-If you experienced change, is the change only related to this concrete implementation you were working on or your leadership in general? Has your leadership changed over and above the current implementation?

Attitudes:

-Was it possible to transfer what you learnt in the training to your colleagues/employees at your unit?

-What was easier and more challenging in that translation work? Which parts have worked and which did not?

-Was there a specific person that was particular supportive/hindering when it comes to spreading your knowledge?

-What do you think your second line manager and senior management would have needed to support your and your employees' change?

-What in the training was the most important part for you to be able to transfer your knowledge from the training into practice?

-Did you miss something in the training? What would you have needed to transfer what you have learned to your workplace/employees?

-Is there something else that you have been thinking about related to the training?

Effects of the training:

-Do you monitor what you have been working on? What do you do?

-How much help and support was the training to your implementation process on a scale from 1 to 10? Can you further develop why it was a [number between 1 and 10].

-How well did your action plan work at your workplace on a scale from 1 to 10? Can you further develop why it was a [number between 1 and 10].

-To what extent was the intervention plan translated into practice on a scale from 1 to 10? Can you further develop why it was a [number between 1 and 10].

Context:

-Was there something in the organization or context that affected your work with the implementation and leading the implementation?

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-5
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	7-9
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	12-13
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*9-10*
Bias	9	Describe any efforts to address potential sources of bias	24-25
Study size	10	Explain how the study size was arrived at	8-9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	14
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	14
		(*b*) Describe any methods used to examine subgroups and interactions	14
		(*c*) Explain how missing data were addressed	14
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	9
		(*e*) Describe any sensitivity analyses	-

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	9
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7-8
		(b) Indicate number of participants with missing data for each variable of interest	9,15,16-18
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	9
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*9,12*
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	-
		Cross-sectional study—Report numbers of outcome events or summary measures	-
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	15,16-18
		(*b*) Report category boundaries when continuous variables were categorized	-
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	21
Discussion			
Key results	18	Summarise key results with reference to study objectives	20
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	22-25
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	25
Generalisability	21	Discuss the generalisability (external validity) of the study results	22-25
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	25

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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iLead- Evaluation of a generic implementation leadership intervention: A mixed method pre-post intervention design

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iLead- Evaluation of a generic implementation leadership intervention: A mixed method pre-post intervention design

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Abstract

Objectives: The present study is an evaluation of the iLead intervention. We also investigate whether or not transfer of training can be supported by contextualizing the intervention (recruiting all managers from one branch of the organization while focusing on one implementation case, as well as training senior management).

Design: A pre-post evaluation design was applied using mixed methods with process and effect surveys and interviews to measure the effects on three levels.

Setting: Healthcare managers from Stockholm's regional healthcare organization were invited to the training.

Participants: 52 managers participated in the iLead intervention. Group 1 consisted of 21 managers from different organizations and with different implementation cases. Group 2, representing the contextualized group, consisted of 31 managers from the same organization, working on the same implementation case, where senior management also received training.

Intervention: iLead is an intervention where healthcare managers are trained in implementation leadership based on the full range leadership model (FRLM).

Primary outcome measures: Reactions, knowledge and implementation leadership are measured.

Results: Quantitative and qualitative analyses indicate that iLead was perceived to be of high quality and capable of increasing participants' knowledge. Mixed effects were found regarding changes in behaviors. The contextualization did not have a boosting effect on behavior change. Hence, group 2 did not increase their active implementation leadership in comparison to group 1.

Conclusion: iLead introduces a new approach to how implementation leadership can be trained when knowledge of effective leadership for implementations is combined with findings on the importance of environmental factors for the transfer of training. Even though managers reported general positive effects, transfer was not facilitated through the contextualization of the intervention. There is a need to further develop approaches to help participants subsequently apply the learned skills in their work environment.

Keywords: contextualization, full-range leadership model, implementation leadership training, intervention, contextualization, organizational development

Strengths and limitations of this study

-The present study is based on a rigorous evaluation process of the iLead intervention using mixed methods, where the quantitative evaluation method is followed up by interviews to get a deep understanding of the effects.

-Effects of the iLead intervention are measured on different levels based on a thorough theory-based evaluation plan.

-Effects of the iLead intervention are, in addition to self-reports, measured through employee-ratings, where employees report on their managers' implementation leadership related to a current implementation.

- Multilevel modelling is applied to account for the nestedness of data, which is the case for longitudinal data.

-Drop out was more prominent in one intervention group and the response rate decreased over time.

Background

Implementing the ever-growing number of evidence-based methods into practice is an integral part of daily work in healthcare organizations. For implementation to be successful, leadership has been identified as a central factor [1–10]. However, many managers lack formal training in leadership and leading change, as they have often been promoted for their work as front-line providers [cf. 11]. In addition, existing studies on leadership during implementation have often lacked a theoretical underpinning [4–6,12], which prevents knowledge about how and why leadership is important for successful implementation. Accordingly, there is little research on how to train managers in leadership that facilitates the implementation process [e.g., 5]. Whereas there is some evidence for the effectiveness of training leaders in implementing evidence-based practice (e.g., EBP [13]) or specific evidence-based methods (e.g., preventing diabetic foot ulcers [14]), little is known about how to train generic implementation leadership (i.e., implementation leadership that can be used across various implementation efforts), a skill that is needed when leaders are expected to lead multiple simultaneous implementations as part of their daily work. The present study is an evaluation of the iLead intervention that aims to train managers in these generic implementation leadership skills [15] answering to calls highlighting the need to provide and evaluate trainings directed at individuals in implementation roles and therefore focusing on implementation practice [16,17].

The iLead intervention

A large amount of leadership research has been based on the full-range leadership model (FRLM) [18,19] that describes both desired active leadership behaviors (i.e., transformational leadership and contingent reward) and undesired passive behaviors (i.e., management by exception and laissez faire). Active leadership has been related to positive organizational and

employee outcomes [7,20–24] and fostering change [7,9,25]. Even though the FRLM has only been used in a few studies that investigated implementation [e.g., 13], systematic reviews have identified leadership activities important for implementation that map well on the active leadership behaviors of the FRLM [5,6,10,26]. Based on this work, the FRLM was used in the iLead intervention [for the study protocol, see 15].

Fostering transfer through a supporting organizational context

Even though leadership development in general has been found to result in positive effects [7,27,28], it has been acknowledged that these often are limited to proximal outcomes such as reactions and knowledge [27,29]. Only 10% of training expenditure has been estimated to translate into behavioral change [30]. This highlights the transfer gap—the difficulty in translating knowledge and skills to the work setting [31].

Three primary factors influence the transfer of training: trainee characteristics, intervention design and delivery, as well as the post-training work environment [32]. Trainee characteristics include personality, the motivation to participate and existing skills, whereas intervention design and delivery defines the objectives of the training and the applied pedagogical methods that are used to bring about skills. The post-training work environment refers to the organizational context of participants, such as social support, transfer climate and the opportunity to perform and follow up of the new skills. Even though trainee characteristics could be used for the selection of participants, this is often not possible in practice; hence, the intervention design and the post-training work environment are factors that can be proactively tackled by interventionists to leverage transfer [cf. 33]. Therefore, in designing the iLead intervention, pedagogical tools to facilitating transfer were focused on (i.e., how the iLead workshops were brought about) (see upper part of table 1). Moreover, a feature that sets iLead apart from other interventions is its effort to further foster transfer by

incorporating a contextualized intervention group to also modify the training work environment. Here senior management (i.e., a team of individuals at the highest level of the organization) and all first-line managers from one organizational branch participated in the training and worked on the same implementation case (see lower part of table 1). Involving senior management is important as they not only allocate resources and have the authority to restructure processes and structures to make the implementation work [34], they also generate and help maintain managers' and employees' commitment [35] and compliance with an intervention [36].

_____Table 1 about here_____

Table 1. Intervention design and post training work environment factors to facilitate transfer of training and the operationalization in the iLead intervention

	Facilitators for transfer of training	**Elements in the iLead intervention**	**Intervention group**
Intervention design	Behavioral modeling	Role play, planning their actions and practicing between workshops	1 & 2
	Error management	Role play, practicing between workshops and revising the action plan, one workshop on handling resistance and continuous problem solving	1 & 2
	Realistic training environment	Working on an ongoing implementation, practicing between workshops, examples from health care in the workshops	1 & 2

Training work environment	Peer and supervisor support	All first-line managers from one organization, in addition to a senior manager intervention	2
	Transfer climate	Interventions on different levels in the organization to create a shared mental model about implementation	2
	Opportunity to perform	One common implementation and the support of senior management to create alignment and direction	2
	Follow up structure	One common implementation and the support of senior management to create alignment and direction	2

The present study

The overall aim of this study is to examine the primary outcomes of iLead, an intervention based on the FRLM [18,19] to train healthcare managers' generic implementation leadership. Based on Kirkpatrick's four-level evaluation model [37], four questions are addressed with a mixed-method evaluation:

1. How do managers perceive iLead?
2. Does iLead increase managers' knowledge related to implementation leadership?
3. Does iLead increase managers' skills in leading a current implementation?

Furthermore, we investigate under which conditions the iLead intervention has greater impact by studying the contextualization of the intervention. Thus, two intervention conditions were compared: an individualized group (group 1) and a contextualized group

(group 2). We expect no difference between the intervention groups regarding to their reactions and learning because both groups were exposed to the same intervention content and pedagogy. In contrast, we expect that contextualization (group 2) will facilitate the transfer of training resulting in the fourth question:

4. Does iLead result in a larger change of the behavioral outcome, i.e. generic implementation leadership, in group 2?

Method

A mixed-methods pre-post evaluation approach was applied with a two-armed, non-randomized intervention design in which managers—based on their organizational belonging—were assigned to one of the two intervention groups.

Setting and participants in the intervention

Healthcare managers from Stockholm's regional healthcare organization, which offers primary, psychiatric, rehabilitation and habilitation services as well as acute hospital care, were invited to participate in an implementation leadership training. More detailed information about the recruitment process can be found in the study protocol [15]. In total, 52 managers participated (see table 2). The majority of managers worked as first-line managers (i.e., worked closest to and had managerial responsibility over operating staff) having responsibility for staff, budget as well as administration for one unit. The majority of managers were responsibility for one unit, whereas some managers had leadership responsibility for several small units (< 5 employees). In intervention group 1, two managers had second-line responsibility.

Group 1 consisted of 21 managers from different branches of the healthcare organization who work with different implementation cases during the intervention. Group 2 consisted of

31 managers from one division of the regional healthcare organization, where senior management (the chief operating manager together with second-line managers) made participation in the training mandatory. In practice that meant that first-line managers in group 2 were given time to participate in the intervention as a form of competence development. In reconciliation with senior management, one first-line manager decided to not participate in the training due to an on-going major reorganization of his/her unit. With some exceptions, first-line managers worked with the same implementation case, which was determined by senior management.

____Table 2 about here____

Table 2. Descriptive statistics of managers in the two intervention groups

	Intervention group 1 (individualized group)	Intervention group 2 (contextualized group)
Number of participants	21	31
Total attrition	11	4
Dropout		
– Before the start of the intervention	3	2
– After WS1/2	3	1
– After WS3	1	1
– After WS4	1	-
Women	92.3%	96%
Age	50 (9.1)	50.8 (8.3)
University education	73.3%	81.3%

Years being a manager	3.3 (2.09) [0.2-9]	4.4 (3.9) [0.5-13]
Number of employees	25.15 (12.70) [5-50]	21.83 (7.78) [8-39]

Notes: means and standard deviations (SD) are presented for age, years as manager and number of employees. Range [minimum – maximum] is presented for years as manager and total number of employees.

The two groups of managers had similar demographic characteristics, which are representative of employees in the Swedish healthcare sector [38] (see table 2).

Attrition was greater for group 1 (for details and time of drop out see table 2). On average, managers from group 1 participated in three out of the four training occasions (SD=.84), whereas managers from group 2 participated on 3.5 occasions (SD=.79).

Intervention

The iLead intervention consists of five half-day workshops, which were provided at four occasions. The intervention content was the same for intervention groups 1 and 2. More detailed information about the development and content of iLead can be found in the study protocol [15] as well as in supplementary file 1.

Patient and public involvement

When the iLead intervention was designed a good fit between the intervention, the healthcare context and participants' needs was ensured through the involvement of five national experts in implementation and leadership training (consults or researchers in the area), 31 first line managers, and nine senior managers participated in a co-created program logic process, generating attitudes, skills and behaviors of successful implementation leaders. The output was used to define intervention goals and activities [for more information see 39]. Patient's involvement was not applicable in this study.

Data sources for the evaluation

A sequential exploratory design was used [40]. Quantitative surveys were conducted prior and twice after the intervention followed with qualitative interviews to enhance our understanding of the training impact. Shorter process evaluation surveys were also conducted after each individual workshop. To strengthen the research design, the participating managers, as well as their employees, were included in the data collection (for an overview see Figure 1).

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Table 3 shows response rates for the effect and process evaluations. Response rates decreased over time, which is common in longitudinal studies [41].

___Figure 1 about here_____

____Table 3 about here____

Table 3. Response rates for managers and employees

	Process evaluation (self-rated manager data)				Effect evaluation (employee data)		
	WS1/2	WS3	WS4	WS5	Pre-test	Post-test 1	Post-test 2
Group 1	15/18 (83.3%)	10/15 (66.6%)	8/14 (57.1%)	10/10 (100%)	252/477 (52.8%)	160/368 (43.4%)	132/268 (49.2%)
Group 2	26/29 (89.5%)	23/28 (82.1%)	22/27 (81.4%)	22/27 (81.4%)	432/607 (71.1%)	313/562 (55.6%)	292/544 (53.6%)

Nine individual semi-structured interviews were conducted by a researcher who was not involved in the intervention. The interview guide was developed based on Kirkpatrick's evaluation model and Baldwin and Ford's transfer of training model [32,37] (for the interview

guide, see appendix). Interviews, which lasted for approximately one hour, took place at the respondents' work places and were recorded and transcribed verbatim by an external transcription service.

Measures in the process evaluation and pre-post effect evaluation surveys

Measurements are described in Table 4.

___Table 4 about here_

Table 4. Constructs in the process evaluation and pre and post intervention surveys

Research question	Construct	Content	No. of items	Response alternatives	Reference	Time of measurement	Cronbach's alpha
Process evaluation (self-rated manager data)							
1	Appraisal of the intervention as a whole	Complexity, relevance, novelty, valence involvement	10	ten-point continuum for each adjective pair	[42]	WS5	.81 .68 .84 .60 .29
2	Knowledge about implementation and		6	1 (strongly disagree) - 10 (strongly	specially constructed to match	WS1/2, WS3,	.90 .97

	implementation leadership			agree)	the iLead intervention	WS4, WS5	.93 .97
		Pre and post intervention surveys (employee data)					
3	Changes in implementation and leadership	Extent of perceived changes in the implementation of the new method as well in the manager's leadership during the last six months	2	1 (big impairment) - 5 (no change) to 10 (great improvement)	[43,44]	T2 T3	.79 .74
4	Active implementation leadership	Leadership behaviors in line with FRLM related to the implementation	13	1 (strongly disagree)- 5 (strongly agree)	[45]	T2 T3	.95 .96

Notes: WS= workshop, T2= post measure 1, T3= post measure 2

Analyses

Multilevel modeling was used to analyze data based on three or more repeated measurements to account for the hierarchical nature of the data [46]. Two-level models with the repeated measure at the first level and the individual person at the second level—the individual employee at the first level and the group belongingness at the second level, respectively—were constructed. Nested models were compared by using full maximum-likelihood estimation [46]. Time was centered on the baseline, respectively WS1/2, whereas the group remained uncentered (0=intervention group 1, 1=intervention group 2). The multi-level models were run in Mplus 7.2, whereas all other analyses were conducted in SPSS 24.

Interviews were analyzed using thematic data analysis [47]. A semantic approach was used, (i.e., the explicit meaning of the data was analyzed). Patterns in the narrative material that captured something important in relation to the above-outlined evaluation models were selected [32,37]. Next, the themes were reviewed by the research team. A few themes were revised or excluded because they overlapped with other themes or were less prevalent (raised by less than three respondents).

Results

Reactions to the intervention

Participants were satisfied (ratings over 7 out of maximum 10) with the training's complexity, relevance, valence, their involvement and the novelty of the content. No group differences were found (see table 5), which is in line with our expectations. The quantitative results were strengthened by interview data (for quotes, see the bottom of table 5). In the analysis two themes emerged. First, managers emphasized that they were able to work hands-

on with their implementation cases, which differed from other trainings they had attended (Quote 1). Moreover, they highlighted the usefulness of the action plan guiding their implementation work during the iLead intervention, which made their intuitive knowledge of the implementation process more explicit (Quote 2) and helped them clarify the implementation for employees. Secondly, the use of role play was perceived to be influential on the managers' development and understanding (Quote 3).

___ Table 5 about here___

Table 5. Reactions to the intervention and related quotes

	Complexity	Relevance	Valence	Involvement	Novelty
Group 1	9.15	9.35	9.15	8.85	7.85
Group 2	8.52	9.06	8.63	8.56	7.09
Difference	$t_{(30)}$=.99	$t_{(30)}$=.58	$t_{(30)}$=.90	$t_{(30)}$=.55	$t_{(30)}$=1.63

Notes: independent t-test did not reveal significant differences between the two groups

Interview quotes	
Quote 1	ID7: What has been the best, and most beneficial, for me was to be very concrete. Often when participating in various kinds of education programs, you get a theoretical top-up in some way, and then there is usually another step where you as a participant need to think about how to work with this in your practice alone. It is pretty easy to get stuck in this process and fail to

	follow through... //
Quote 2	ID 9: …when I got to see this training, I felt that I was pretty good at implementation, simply out of experience. I have learned through experience. But what I haven't done is a structured implementation action plan, previously I had gone through the steps only in my head. This structured process plan, I feel…will give me an enormous strength in the future.
Quote 3	ID2: Yes, I really appreciated those exercises, both when we were to give a talk [about our implementation case] and catch the others' interest, and then this exercise where there was a challenge...where there was a group that had been told to have different opinions [about the implementation case] and then a manager tried to handle that. // I think that was very valuable. Role plays and when you get to practice with each other, that helped me a lot.

Improvements in implementation leadership knowledge

Managers reported an increase in knowledge about implementation and how to lead this process over time and no differences between intervention groups was detected (see Table 6), which is in line with our expectations. In the interviews, managers expressed increased knowledge concerning implementation leadership as a generic skill, the structure and the iterative nature of the implementation process (see Table 6, Quote 4 & 5) and the possibility to lead an implementation decoupled from knowledge about the specific content of the implementation (Quote 6).

__Table 6 about here ___

Table 6. Multilevel models predicting change in knowledge and related quotes

	Knowledge (ICC=.44)		
	Model 1	Model 2	Model 3
Intercept	6.92*	5.97*	6.37*
Time		.41*	.42*
Group			-.62
σ^2_e	1,39*	1,10*	1,10*
σ^2_{u0}	1,12*	1,20*	1,11*
-2*log(lh)	497.62	474.3	471.8
df	3	4	5
Δ-2*log(lh)		23.3*	2.5
Δ_{df}		1	1
Pseudo R_1^2			.21
Pseudo R_2^2			.01

Note: Table entries represent unstandardized parameter estimates. Individual level: N =128-140; group level: N =42. Time is centered at WS1/2, intervention group is coded 0=intervention group 1 and 1=intervention group 2, *p<.05.

Interview quotes	
Quote 4	ID9: ... I have become more conscious and more structured concerning what I need to think about when working through the different steps [of the implementation], and also the clarification of what behavior it is that I want to change.
Quote 5	ID1: It is not a failure that it didn't go well… //…like, okay, we tried

something, oh well—let's try again, and in this way you can proceed. So, it [the action plan for the implementation] is not finished when you launch it.

Quote 6 ID7: //…the *leading* aspect is somehow something you can learn; to implement something new without having to have deep knowledge of the particular [implementation case]…then I can feel more confident in managing restructurings. //…previously when I have been manager and implemented quality registries…//…I think I lost myself in the content [of the implementation] in some way…//

Improvements in implementation leadership behavior

When reviewing the last six months, employees experienced an improvement in implementation and their manager's leadership practices. No difference was found between the intervention groups (see Table 7, left side). Active implementation leadership at T2 did not differ between groups nor did group 2 have a steeper increase in implementation leadership between T2 and T3 (see Table 7, right side).

__Table 7 about here____

Table 7. Multilevel Estimates for Models predicting implementation leadership (employee ratings)

	CP T2 (ICC=.035)		CP T3 (ICC=.16)		AIL T2 (ICC=.26)		AIL T3 (ICC=.49)	
	Model 1	Model 2	Model 1	Model 2	Model 1	Model 2	Model 1	Model 2
Intercept	6.10*	.6.36*	5.93*	3.36*	3.76*	3.70*	3.64*	.97*

CP[a]/AIL	-	-	.42*	-		-	.73*	
[b] T2			[a]				[b]	
Group		-.42	.06		.10		-.12	
σ^2_e	2.63	2.64	2.65	2.33	.65*	.65.	.62*	.35*
	*	*	*			23*		
σ^2_{u0}	.09	.04	.51*	.39	.24*		.60*	.18*
-2*log(lh)	660.67	658.3	728.4	645.6	436.74	426.5	486.46	336.0
df	3	4	3	5	3	4	3	5
Δ-2*log(lh)		2.4		82.8		.2		150.5*
			*					
Δ_{df}		1		2		1		2
Pseudo R_1^2		- .003		.12		.002		.43
Pseudo R_2^2		.55		.23		.004		.69

Note: unstandardized coefficients, CP= Changes in leadership procedures, AIL= Active implementation leadership, *p<.05.

To sum up, employees experienced a positive change in both the implementation process and their manager's leadership practices, but no difference between groups could be found regarding an increase in active implementation leadership. Interviews provided a deeper insight in what participants perceived as particularly valuable and provide examples on altered ways of leading implementations. However, the boosting effect of the contextualization, which should facilitate a transfer of training for group 2, was absent. It became clear that varying attitudes toward the common implementation case (Table 8, quotes 7), the timing of the iLead intervention in relation to a concurrent major organizational change (Table 8, quotes 8) and a perceived lack of support from senior management and peers

(Table 8, quotes 9) may have mitigated the impact that the contextualization had on the outcomes.

__Table 8 about here____

Table 8. Quotes related to the contextualization

	Interview quotes
Quote 7	ID11: It was in the midst of this reorganization when managers were dealing with crying employees who were going to be transferred and so on. And then one was asked to focus on implementing the new [common] program. There must have been a lot of other cases that we could have implemented that would have been more appropriate to implement at this moment in time…
Quote 8	Id 7: I think that it was unfortunate that we were in the midst of the reorganization while the training program was simultaneously running. I think that it was very interesting to participate in the training and that it is very important for all of us to do this. However, I think that employees may have been in a slightly different mindset as a result of the reorganization, and were more concerned about how things would change in their daily job (e.g., who they were going to collaborate with later that year, what unit they would belong to, etc.). Change happens, but on this scale – once in a decade, maybe, so it is not very often.
Quote 9	ID14: I feel that they [the senior management] have not been able to fully handle the situation [with supporting line managers as part of the training], which I believe—yet again—is the result of the timing. If it was not for the

reorganization that was occurring in the midst of everything, then I think the senior management would have focused more on supporting us.

Discussion

This study focuses on the outcomes of iLead, an intervention training healthcare managers' generic implementation leadership. Results showed that managers perceived the content, as well as the pedagogy of the intervention to be relevant and of high quality. Moreover, they perceived that their knowledge about implementation leadership had increased throughout the intervention. However, behavioral effects were mixed. The employee transition ratings on the progress regarding the implementation and the leading of it indicated an improvement. This was mirrored in the interviews in narratives about altered ways of thinking about implementation and how to lead it. Despite our attempt to facilitate transfer by contextualizing iLead, by offering interventions to both first-line and senior managers (chief operating manager and second-line managers) from one organization and working on the same implementation case, no difference between the two intervention groups in implementation leadership or its increase over time could be found.

According to previous literature transfer of training may be facilitated when there is a common understanding about implementation, alignment across hierarchical levels and social support among colleagues and from senior managers [34–36,48]. Based on this, the interviews with managers provided insight into why the contextualization of iLead might not have resulted in the anticipated boosting effect.

First, first-line managers' attitudes regarding the common implementation case (decided by the senior management) were clearly mixed. Some embraced it, others were opposed to it, and that had been so for a long time: The implementation had been ongoing for some years with several setbacks. The fact that senior management made it mandatory to focus on this specific

implementation case in the iLead intervention caused frustration. Thus, it seems likely that the readiness for the implementation case differed between the intervention groups. Managers in group 1, who were free to choose their implementation case, possibly experienced higher readiness for their implementation case than managers from group 2, who were expected to work with a particular implementation. This may have decreased the managers' ability to make the most out of the exercises in the iLead intervention, which resulted in reoccurring discussions about the feasibility of the implementation case in the workshops for group 2. This presents the challenge of separating attitudes and experiences of the leadership training and its contextualization from the attitudes and experiences of the implementation case. Nevertheless, it also points toward the importance of the fit between the perceived needs of the organization and the evidence-based practice that is implemented [e.g., 2,49,50]. Moreover, there also needs to be a shared perception of managers on different levels regarding the importance of implementing the evidence-based practice under question. Hence, even when the focus of an intervention is on implementation leadership such as iLead, rather than a specific evidence-based practice [e.g., 13,14], it may still be necessary to offer support to the organizations and participating managers to ensure the feasibility of the implementation case before accepting participants for this kind of intervention.

Second, major organizational change concurrently occurred with the intervention. In group 2, managers described conflicting focus, both for themselves and for employees, due to major organizational change (merging or closure of units, change in first-line managers as well as change of employees within units). However, managers from group 1 also experienced organizational changes, yet they reacted differently. They mentioned the changes, but did not pay as much attention to them, nor did they describe them as a major hindrance in participating in the intervention and conducting the implementation. Yet, in group 1, attrition was higher, which might have been a consequence of a conflicting focus.

The impact of managers' attitudes toward the common implementation and the timing of the iLead intervention and organizational change in group 2 may be elucidated by research on mental models [34]. Mental models concern underlying psychological beliefs, which affect participants' reactions and behaviors. Even though the quantitative evaluation of the iLead intervention revealed positive reactions, the interviews indicated mixed—in some cases, critical—beliefs regarding the implementation case and the timing of the organizational change. For an intervention and its implementation to be effective, the participants should believe that there is a problem that the intervention is suitable to address, which motivates them to participate in the intervention activities [51]. Whereas no difference in intrinsic motivation to participate in iLead was found between the two intervention groups, extrinsic motivation was higher in group 2 (analysis can be obtained from the authors). This is possibly a consequence of senior management making both the training and the implementation case mandatory for the first-line managers.

Third, when whole organizations undergo an intervention, the group dynamics and existing organizational culture is brought into the intervention. Consequently, skeptical or conflicting mental models about the intervention or the implementation case can receive more attention and need to be addressed. For example, for group 2, workshop leaders had to spend more time on managing issues that originated from the organizational context (e.g., the skeptical attitude toward the common implementation case). In addition, in the contextualized group senior management took part in an intervention of their own, aiming to support first-line managers. However, this support was only partly perceived by first-line managers. Even though senior management themselves developed through this intervention [for more information, see 52], it did not result in a sufficient alignment between organizational levels. The timing of the senior management intervention in relation to first-line managers' intervention may have been suboptimal. Important discussions that would have had the potential to facilitate the

implementation process, if issued earlier, emerged among senior management during their intervention. More preparation time to define the implementation case and senior management's role in supporting first-line managers in their implementation process might have been beneficial and should be adjusted in future multi-level interventions [52].

In sum, although contextualization may theoretically have several benefits, such as providing social support, direction and alignment of the implementation to boost transfer, this study highlights several impeding factors that may have outbalanced these potentially beneficial effects. A more thorough organizational analysis prior to the intervention to identify barriers for the intervention and the implementation case is recommended. Hence, the general implementation and group climate, the history with the implementation case and the structure and opportunities to perform in line with the implementation should be investigated, along with participants' capacity and readiness for this implementation. Based on this analysis, preparatory workshops for the actual intervention should be provided. Even though the content of the parallel first-line manager and senior management interventions should be retained, more elements fostering the dialog between the different managerial levels should be included [52].

Strengths and limitations

This study has several strengths that should be highlighted. First, iLead is a generic intervention that is theory driven and has been developed involving relevant stakeholders (e.g., line and senior management). It is based on the FRLM, which mirrors relevant leadership behaviors that were also previously identified in implementation research [5–10,26]. As it has been highlighted that general active leadership is not sufficient to reach specific results (e.g., a successful implementation) [20,53], iLead focuses on active implementation leadership. Second, to evaluate iLead, a sophisticated longitudinal

multisource design has been applied using both quantitative and qualitative data, which made it possible to capture the intervention context and ongoing process to understand the effects of iLead. Third, evaluation was facilitated by the iLead scale [54], capturing implementation leadership of the specific implementation case. The scale was specifically developed for this purpose, as it has been highlighted that the utilized evaluation criterion needs to be aligned with the intervention content [55]. The iLead scale can also be a useful tool in practice to provide mangers with feedback regarding their implementation leadership.

The current study has also some shortcomings that must be acknowledged. First, the recruitment processes for the intervention and assignment to the two intervention groups might have introduced a systematic bias. Randomization of managers was not possible, and we cannot exclude that intervention groups differed systematically. Moreover, drop out varied between the groups, which might have affected the generalizability of results, particularly for group 1. Furthermore, the lack of randomization makes it impossible to separate effects of time from effects of the intervention, hence, an evaluation framework and multiple data sources were used to mitigate the risk of erroneous conclusions. Second, some outcomes (reactions and learning) relied on self-reports, which can be biased through common method bias [56,57]. Third, to investigate behavior change as an effect of the iLead intervention transition rating questions where used. Transition ratings are ascribed to overestimate effect sizes [58] as well as being influenced by the present state bias [59,60]. These biases could however not be found in a recent study comparing different ways of assessing change [61]. A traditional pre-post evaluation measurement was not feasible for several reasons. First, the iLead scale [45] could only be administered at the two follow up measurements because managers were still undecided regarding their implementation case when the baseline measurement was conducted pre intervention. Moreover, a comparison of overall mean changes pre-post intervention might not to be feasible in iLead, where each manager's work

took its starting point in her/his specific stage of her/his specific implementation case to assure the perceived usability of the intervention. Even in the contextualized intervention group, where the same implementation case was a focus, local conditions varied and led to different time plans. Hence, timely aligned of measurement with managers' individual change processes [62] is challenging with individualized interventions when the implementation process does not follow the time frame of the intervention; that is, when managers differ in their implementation progress and, therefore, vary in their ability to show implementation leadership. In addition, managers set individual leadership goals based on their strengths, weaknesses and work group needs. While probably beneficial for the individual participant, tailoring the intervention to the participants created a large variation of goals and pace in the implementation. Fourth, healthcare organizations are fast-moving entities with high turnover [63], resulting in changes in the work unit composition across measurement times manifesting in different sample sizes for the analyses. Only a smaller group could be followed across all three time points. In addition, whereas iLead focused on active implementation leadership, recent research shows that destructive leadership has detrimental effects [20,64]; hence, including how to decrease passive leadership in leadership trainings is another avenue for future research.

Conclusions

This study shows that a generic implementation leadership training that is based on the FRLM may lead to positive outcomes in participating managers' reactions and implementation knowledge. However, it also shows how hard it is to achieve transfer from training to behavioral change. Efforts to support transfer through contextualization was not successful. Potential explanations are offered by interview data, which suggest a counter effect of impeding organizational factors. Hence, contextualization may not be sufficient to

counterbalance such factors, calling for a thorough organizational analysis to identify hindering factors for the implementation beforehand.

Abbreviations

FRLM - full range leadership model

EBP - evidence-based practice

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Ethical approval and consent

All procedures were approved by the regional research ethics committees in Stockholm, Sweden (ref no. 2015/857-31/5). Written informed consent was obtained for all study participants.

Patient consent Not required.

Availability of data and materials

The analyzed dataset used for this study is available from Dr. Anne Richter (anne.richter@ki.se) on reasonable request.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

Authors' contribution

AR: Study conception and design, Acquisition of data, Analysis and interpretation of data, Drafting of manuscript, Critical revision

CL: Analysis and interpretation of data, Drafting of manuscript, Critical revision

HH: Study conception and design, Acquisition of data, Analysis and interpretation of data, Drafting of manuscript, Critical revision

UVTS: Study conception and design, Acquisition of data, Analysis and interpretation of data, Drafting of manuscript, Critical revision

RL: Interpretation of Data, Drafting of manuscript, Critical revision

RM: Analysis and interpretation of data, Drafting of manuscript, Critical revision

TH: Interpretation of Data, Critical revision

UES: Acquisition of qualitative data, Analysis and interpretation of qualitative data

All authors approved the final version.

1

2 **Word count**

3 3668

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Figure legend

– Figure 1. Evaluation design for iLead

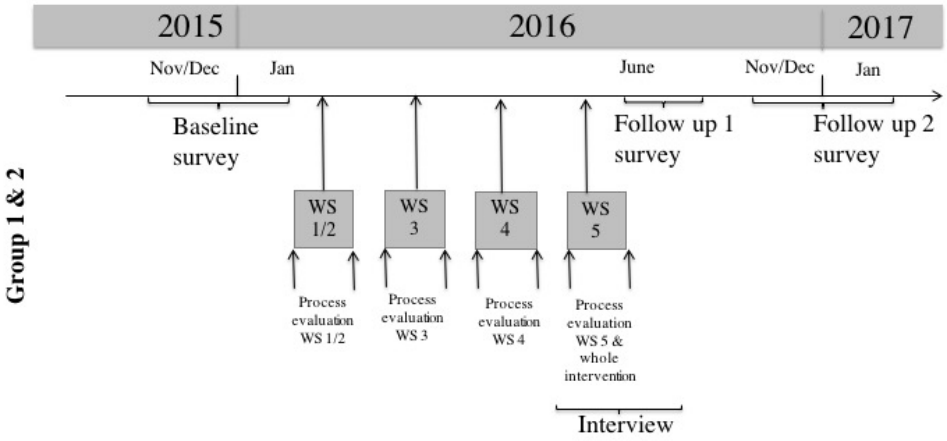

Figure 1. Evaluation design for iLead

253x116mm (72 x 72 DPI)

Intervention content

Workshops 1&2 Implementation and leadership 2 x 3 hours	**Workshop 3 Communicating the implementation 3 hours**	**Workshop 4 Supporting the implementation 3 hours**	**Workshop 5 Sustaining the implementation 3 hours**
Aim: use an evidence-based model on implementation and connect leadership to it as an implementation strategy	Aim: inspirational and motivational communication of the implementation	Aim: understand and handle employee reactions to the implementation	Aim: planning for sustainability of the implementation
Introduction to the implementation model based on the Behavioral Change Wheel Applying the model to a current implementation Introduction to the full range leadership model Receiving the 180 degree on feedback report on general and implementation-	Follow-up on the between-workshop assignment Action plan finalization – identifying, pin-pointing and analyzing manager implementation leadership behaviors to enable and facilitate employee target behaviors Introduction to inspirational motivation	Follow-up on the between-workshop assignment Repetition of the steps in the implementation model Understanding employee reactions and resistance to implementation Training of possible implementation leadership behaviors to overcome resistance and to support the	Follow-up on the between-workshop assignment Apply the implementation model to a fictive example Action plan follow-up and revision focusing on evaluation and follow up. Introduction to continuously evaluating the implementation progress.

specific leadership behaviors, understanding and analyzing feedback on implementation leadership Action plan initiation – identifying, pin-pointing and analyzing employee target behaviors of the implementation Assignment to work with between Workshops 1/2 and 3: discuss the results of the feedback report with the employees & discuss one's own prerequisites for implementation leadership with senior manager	Training of inspirational and motivational communication in relation to the action plan Assignment to work with between Workshops 3 and 4: Present the action plan to the senior manager as well as employees, that will be involved in the implementation. Act in line with the action plan.	implementation Introduction to contingent reward, intellectual stimulation and individual consideration Revision of the action plan Assignment to work with between Workshops 4 and 5: Act according to the action plan, evaluate the progress related to the implementation. Testing contingent reward, intellectual stimulation and individual consideration. Identify potential obstacles with the action plan.	Focus on intervention sustainment – measuring and monitoring change, conducting adaptations Transform the action plan into a sustainability plan

Core components that are used in all workshops:

Work with one's own implementation case
Short expert lectures presenting state-of the art research
Individual as well as reflection in small groups
Role-play
Individual feedback from employees, i.e., 180-degree feedback in feedback report
Feedback from fellow training participants
Feedback from workshop leaders

Work between the workshops
Booster email between the workshops

Appendix 1. Interview guide

Introduction:

Can you describe your role as a manager?

Transfer of knowledge to practice:

-What have you learnt from the training? How have you used what you have learnt in the training?

-Have you learnt something during the training that you are keen to use related to your leadership? Something that stands out as particularly important?

-Which parts of the training did you perceive to good and where there parts that were missing?

-Have you had the chance to use what you have learnt during the training? Can you provide examples?

-Can you recall a work situation when it worked well to use what you learnt in the training? What do you think was the reason for why it went well?

-Do you think there will be more of these situations where you will be able to use the things you learnt in the training?

-Where there situations where you used something from the training in a different way? Did that result in the desired outcome? And why?

-Have you experience difficulties in using what you have learnt in the training in your practice?

-Have you experienced conflicts between the training and your workplace/practice when you have tried to use the new leadership behaviors?

-Have you experienced something in you or your situation that can make it more difficult to use these new leadership behaviors?

-Can you recall a work situation when it did not work well to use what you have learnt in the training? What do you think was the reason for this?

-What could facilitate that you can use the knowledge from the training? Factors in you or your workplace?

-How much effort have you invested to try using what you have learnt in the training?

-Did you receive the support that you would have needed to use what you learnt in the training? What and which aspects have been supporting?

-If not, which support would you have needed to be able to use what you have learnt in the training at your workplace?

-Do you experience that the training has change your or others way of thinking about the implementation? Can you give concrete examples?

-Do you experience that the training has changed your or others behavior at your workplace? Can you give concrete examples?

-If you experienced change, is the change only related to this concrete implementation you were working on or your leadership in general? Has your leadership changed over and above the current implementation?

Attitudes:

-Was it possible to transfer what you learnt in the training to your colleagues/employees at your unit?

-What was easier and more challenging in that translation work? Which parts have worked and which did not?

-Was there a specific person that was particular supportive/hindering when it comes to spreading your knowledge?

-What do you think your second line manager and senior management would have needed to support your and your employees' change?

-What in the training was the most important part for you to be able to transfer your knowledge from the training into practice?

-Did you miss something in the training? What would you have needed to transfer what you have learned to your workplace/employees?

-Is there something else that you have been thinking about related to the training?

Effects of the training:

-Do you monitor what you have been working on? What do you do?

-How much help and support was the training to your implementation process on a scale from 1 to 10? Can you further develop why it was a [number between 1 and 10].

-How well did your action plan work at your workplace on a scale from 1 to 10? Can you further develop why it was a [number between 1 and 10].

-To what extent was the intervention plan translated into practice on a scale from 1 to 10? Can you further develop why it was a [number between 1 and 10].

Context:

-Was there something in the organization or context that affected your work with the implementation and leading the implementation?

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-5
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	7-9
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	12-13
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*9-10*
Bias	9	Describe any efforts to address potential sources of bias	24-25
Study size	10	Explain how the study size was arrived at	8-9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	14
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	14
		(*b*) Describe any methods used to examine subgroups and interactions	14
		(*c*) Explain how missing data were addressed	14
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	9
		(*e*) Describe any sensitivity analyses	-

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	9
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7-8
		(b) Indicate number of participants with missing data for each variable of interest	9,15,16-18
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	9
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*9,12*
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	-
		Cross-sectional study—Report numbers of outcome events or summary measures	-
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	15,16-18
		(*b*) Report category boundaries when continuous variables were categorized	-
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	21
Discussion			
Key results	18	Summarise key results with reference to study objectives	20
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	22-25
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	25
Generalisability	21	Discuss the generalisability (external validity) of the study results	22-25
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	25

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.