

The side effects of service changes: exploring the longitudinal impact of participation in a randomised controlled trial (DOORWAYS) on staff perceptions of barriers to change

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Research article

Keywords: Mental health wards; Nurses' perceptions; Barriers to change; unstructured multivariate linear regression models

Posted Date: August 12th, 2019

DOI: <https://doi.org/10.21203/rs.2.12594/v1>

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Version of Record: A version of this preprint was published on December 18th, 2019. See the published version at <https://doi.org/10.1186/s12888-019-2370-6>.

Abstract

Background Staff and service users have expressed concerns that service improvements in U.K. mental health wards have been slow or transient. It is possible that certain changes are positive for some (e.g. service users), but negative for others (e.g. staff), which may affect implementation success. In this study, we explore whether a programme of change to improve the therapeutic milieu on mental health wards influenced staff perceptions of barriers to change, 12 months after implementation. Method A cluster randomised controlled trial called DOORWAYS was conducted on eight inner-city U.K. acute mental health wards. Randomisation was achieved using a list randomly generated by a computer. A psychologist trained ward staff (mainly nurses) to deliver evidence-based groups and supported their initial implementation. The impact of these changes was measured over 12 months (when 4 wards were randomised), according to nurses' perceptions of barriers to change (VOCALISE), using unstructured multivariate linear regression models. This innovative analysis method allows maximum use of data in randomised controlled trials with reduced sample sizes due to substantial drop out rates. The contextual influences of occupational status (staff) and of workplace setting (ward) were also considered. Results Staff who participated in the intervention had significantly worse perceptions of barriers to change at follow up. The perceptions of staff in the control group did not change over time. In both groups (N=120), direct care staff had more negative perceptions of barriers to change, and perceptions varied according to ward. Across time, direct care staff in the intervention group became more negative than those in the control group. Conclusion Participation in this program of change, worsened staff perceptions of barriers to change. In addition, occupational status (being from the direct care group) had a negative effect on perceptions of barriers to change, an effect that continued across time and was worse in the intervention group. Those providing direct care should be offered extra support when changes are introduced and through the implementation process. More effort should be placed around reducing the perceived burden of innovation for staff in mental health wards.

Background

Despite global investment into the development of new innovations, relatively few research findings are translated into health care practice (1-3). British acute mental health wards, in particular, have attracted criticism over recent decades for being slow to deliver improvements in care (4, 5), and for low levels of activity in promoting social engagement and therapeutic interaction (6, 7). More research is clearly needed to examine what prevents such changes from being delivered successfully in these settings.

Understanding how nursing staff respond to changes may be key. To explore barriers to change in mental health wards, this study will examine the impact of a programme of change on staff perceptions 12 months after its implementation. These changes were delivered as part of DOORWAYS, a clinical trial which tested the impact of a range of interventions to improve the therapeutic milieu in eight mental health wards, by training nursing staff to deliver cognitive behaviour therapy based groups (CBT) (8).

Exploring how changes affect nursing staff is important because nurses are the largest staff group working in the NHS. As such, nurses can make a significant contribution to the development and running of the services. In mental health wards, nursing staff are responsible for co-ordinating most of the ward activities. They deliver daily care through extensive interactions with those who are admitted as service users. Their cooperation is essential if ward level changes are required. However, research that explores why mental health staff might have difficulties when incorporating innovation into practice is lacking (9, 10), and the longitudinal impact of changes on staff working in mental health wards has not yet been explored.

In their article, (11) Powell et al. argued in favour of linking implementation strategies to barriers that consider the context of the setting involved. This is important because any impact from health innovations is likely to be influenced by social and organisational factors, which may either enhance or hinder implementation (12). There are a number of contextual reasons why changes may feel difficult for staff working in mental health settings.

First, mental health wards are complex environments, which, even before introducing changes, are prone to volatility and disruption because the client group are acutely unwell and often distressed (13, 14). Indeed, there is some evidence that a challenging ward climate adversely affects how mental health nursing staff respond to changes (15-17). Our previous work also suggests that ward climate affects how staff perceive barriers to change in mental health wards (18). This study develops current evidence by exploring whether different ward settings influenced the perceptions of the staff who worked there, across time.

Second, intensive programmes of change are likely to bring disruption before improvements, and as it is generally well accepted that employees thrive on stability and resist changes that cause uncertainty and disruption (19, 20), it may be that certain staff in mental health wards find changes harder to cope with than they might, in a more stable setting. This may depend on where they are positioned in the organizational hierarchy of the ward. In the general health literature there is evidence that nurses respond differently to changes according to their occupational status, with managers having more positive responses to change than more junior staff (21). In our previous studies, we found that occupational status predicted perceptions of barriers to change in mental health ward staff (22, 23). This study will develop that finding by examining whether staff perceptions in two different occupational categories (senior staff and direct care staff) changed over time, as a result of participation in DOORWAYS.

This study contributes to the field of implementation science by investigating whether nursing participation in a programme of change affected their perceptions of barriers to change. The effects of occupational status and ward climate on perceptions of barriers to change will also be considered.

Hypothesis

Perceptions of barriers to change will be more negative in nursing staff who participated in DOORWAYS compared to those in the control group.

Methods

Study context and trial design

This study uses longitudinal data from nursing staff working within seven inner city, acute in-patient wards, and one specialist in-patient women's service, in a mental health National Health Service Foundation trust. These data were collected for the DOORWAYS trial (8), which was funded and ran from February 2008 until April 2010. DOORWAYS was stepped wedge, cluster randomized controlled trial (RCT) which was designed so that at each randomisation point, two wards were assigned to the therapeutic intervention arm and those on the 'waiting list' provided a control (see figure 1). Data were collected pre-randomisation, so that randomised wards also acted as controls. This meant that at the T1 data collection point, for example, staff on wards 4 and 8 did not know that they would be receiving the intervention next. Those on wards 3 and 5, were aware that they were in the intervention group, and all others were not aware of when they would receive the training. Altogether, there were five randomisation points, which allowed all of the wards to receive the intervention during the course of the trial. The order of ward allocation to the intervention was determined by a randomly generated list, which was computed by a statistician using the *ralloc* procedure in Stata, which is a statistical software package.

This study is concerned with only two time periods; baseline (T0), when no wards had received intervention, and the 12-month follow-up, when 4 out of the eight wards had received the intervention, and were running groups.

Intervention

After randomisation, a clinical psychologist offered training to nursing staff in a number of groups and evidence base activities which included:

- Communication skills – to improve communication between staff and service users, and communication more generally.

- Social Cognition & Interaction Training – to improve service users' understanding of social situations and minimise misunderstandings with others (24).

Wards were also offered a choice of therapeutic activities, which they selected based on their service requirements, as follows:

- Hearing Voices Group - to reduce the distress associated with hearing voices, and to teach new coping skills whilst improving self-esteem (25).
- Self Esteem and Coping with Stigma - to reduce the stigma associated with mental health problems, including the negative self-evaluations which may maintain low self-esteem (26).
- Emotional Coping Skills - to teach skills to service users for coping with overwhelming negative emotions (common in those who self-harm) (27). This group was based on dialectical behavioural therapy.
- Relaxation Techniques – to teach progressive muscle relaxation techniques and breathing exercises to service users in preparation for sleep (26)
- Problem Solving Skills – to teach structured methods for problem-solving and involved identifying the problem, brain storming possible solutions, and selecting the best solution(s) (28).

Implementation followed a change management strategy adapted from 'Diffusion of Innovations' (29). The aim was to identify enthusiastic individuals as champions, which would motivate other members of the team to adopt the intervention. After six months the groups were expected to run regularly because a majority of staff had been trained and involved. After the training, there followed a process of establishing the groups on the wards, through demonstrations by the psychologist. The nursing staff were then asked to deliver the groups independently by the third month. Until the end of six months the psychologist was available for advice and ongoing support. By the twelfth month, all four wards included in this study had received training in communication skills and the intervention groups were running as outlined in figure 2.

Inclusion criteria

All permanently employed nursing staff on acute in-patient wards were eligible to take part in this stage of the study, including staff from band seven (team leaders), band six (clinical charge nurses), band five (entry level qualified staff) and band three (health care assistants).

Sample size

To estimate the number of participants necessary for multi-level regression models we followed the general rule suggested by Green (30) of ten cases per variable. Given N=120 participants were included in a regression model with five variables, this sample was sufficient.

Ethics, consent and permissions

A local NHS Research Ethics Committee (07/H0809/49) awarded ethical approval for this study. Participants were provided with information sheets and given time to consider participation before providing written, informed consent.

Procedure

Staff were recruited to each time point over 30 days by an on-site team of research assistants. All staff measures were completed by self-report. Although it was possible for the same staff to participate at multiple time points, changing shift patterns meant that those who participated at baseline were not necessarily available at follow up, leaving the dataset susceptible to losses. The baseline data were collected in March and April 2009 and the follow up data were collected 12 months later.

Measures

Primary outcome measure: Staff Perceptions of Barriers to Change:

The 18 item Views Of Change and Limitations in In-patient Settings (VOCALISE) measure (22) was developed with direct participation by mental health nurses to capture the reality of working in wards, and multiple causes of resistance to change. Some “barriers to change” reflected organisational difficulties:

- When it comes to change, information is not circulated effectively on my ward;
- I’m too busy to keep up to date with information about the changes that are happening on my ward;
- Poor leadership prevents changes happening on my ward
- Inadequate staffing prevents changes being successful on my ward.

Some described staff reluctance and withdrawal:

- When some staff stop engaging with planned changes resistance spreads through my whole team
- I feel disheartened when others do not want to get involved in changes.

VOCALISE is scored on a 6 point Likert scale ranging from strongly agree to strongly disagree. The highest score is 108, and the lowest is 18. In this study, VOCALISE was reverse scored so that high scores indicated negative perceptions. It can be accessed at www.perceive.iop.kcl.ac.uk.

Secondary outcome measures:

Occupational status: categorized into two groups 1) direct care staff and 2) managers. Direct care staff were healthcare assistants and band 5 qualified nursing staff. Managers were bands six and seven nursing staff (i.e. clinical charge nurses, practice development nurses and team leaders).

Ward climate: an eight-category “ward” variable was used as a proxy measure for ward climate.

Time: two time points were included (baseline, 12-month follow-up).

Treatment group: two groups participated: (intervention and control).

Analysis strategy

As there were a large number of missing data at follow up (only 43% of the baseline sample were repeat participants), we adopted unstructured multivariate linear models.

Unstructured multivariate linear models use both baseline and follow-up data as the correlated outcome, enforcing a zero treatment effect at baseline, with an unstructured covariance matrix for baseline and follow-up measures (31-35). The models allow more information from the data to be used (compared to the traditional ANCOVA model), by also including the individuals who have no outcome measurement, but who do have a baseline measurement. Thus, the number of observations used by unstructured multivariate linear models is larger than the number of observations used by ANCOVA when missing outcome data are present. Moreover, unstructured multivariate linear models also deal with partially missing baseline measurements in RCT’s in the most statistically efficient way when the outcome is measured (34).

Unstructured multivariate linear models are advantageous because they can handle substantial drop out rates in RCT’s in an unbiased way under a ‘missing at random’ (MAR) assumption (36). In our study we used these models to compare VOCALISE at baseline and 12 months, under the assumption of missing at random (a weaker assumption than missing completely at random, which is used in the more traditional ANCOVA model). If data are missing at random, the emphasis is shifted so that, conditional on the fully observed variable (VOCALISE T0), the chance of seeing the partially observed variable (VOCALISE at 12 months) is assumed not to depend on the values of VOCALISE T0. Whether participants withdraw from the trial or remain, the distribution of their data is conditionally the same, because their unobserved future is based on their observed past (37). This approach is also preferable to using multiple

imputation, a less efficient form of this type of analysis, since the two approaches broadly coincide, as the number of imputations gets large

Initially, mean total VOCALISE scores for the repeat participants, will be plotted at both time points to compare the scores of both groups (intervention and control). Then, we will compute an unstructured multivariate linear model to explore the impact of the DOORWAYS intervention at follow up on staff perceptions of barriers to change.

Unstructured multivariate linear model

In the model, the correlated outcome variable will be staff perceptions of barriers to change (VOCALISE) and the main predictors of interest (included as fixed effects) will be as follows:

- Time: the adjusted change in the outcome between baseline and the 12-month follow-up.
- Treatment group (intervention effect): this variable shows the adjusted change in score between groups (control and intervention) at follow up.

In our previous papers, we showed that ward climate and occupational status affected perceptions of barriers to change (18, 23). In this study, ward and occupational status will therefore be included as covariates in the model, as follows:

Considerations for model interpretation

There are some points to note before describing the results because the interpretation of unstructured multivariate linear models for the analysis of RCT data is different from the usual interpretation of linear models.

1. The *intervention effect* variable estimates the difference in group scores at follow up, adjusted for all other included covariates. If coded to provide estimates for those who participated in the intervention wards, it assumes an interaction between group and time because this variable comprises 2 groups: 1) those who were in the control group at follow up and 2) everybody else (baseline sample and those who did receive the intervention at follow up). When the coding is changed to provide estimates for those in the control group, there are then 2 groups: 1) those who were in the intervention group at follow up and 2) everybody else (baseline sample and those who were in the control group at follow up).
2. The models do not measure a main effect of time because as discussed above, an interaction between *time* and the *intervention effect* variable is assumed. The *time* variable allows an estimate

of the adjusted change in the outcome between baseline and follow up. By changing the coding in the *intervention effect* variable, the estimates for the *time* variable are also restricted to the control group only or the intervention group only. And, because there is an interaction between group and time in the intervention effect variable, the effects within each treatment group are expected to be different over time.

3. The constant represents the estimated mean outcome score. As the models adjust for *occupational status*, this score is based on *occupational status* =0 (direct care); and the reference category for ward, which was ward 1, where staff had the most negative perceptions of barriers to change. The constant is the same whether the *intervention effect* variable is coded to represent those who did, or those who did not receive the intervention because of the coding (which enforces a 0 treatment effect at baseline in order to meet the assumptions of an RCT).
4. The estimates for *ward* and *occupational status* are the mean outcome score differences between the different categories of *ward* and *occupational status* across time, given the assumption that both arms of the trial started with the same scores at T0. Therefore, for example, the estimate for *occupational status* is the mean score difference between the two categories of *occupational status*, adjusting for *ward*, *time*, and the *intervention effect* that forces the mean scores to be the same at baseline. The estimates for *ward* and *occupational status* are across time, and are not changed by recoding the variable for *intervention effect*.
5. To aid interpretation of significant estimates, the mean scores of those included in the repeated measures sample will be compared to the mean scores of those included in the full dataset. This will also provide a sense check for the more complicated model results. A figure showing the mean score of the repeated measures sample will be compared to mean VOCALISE scores post hoc, which were calculated using the post estimation command *lincom*, in Stata 14. This command computes point estimates, standard errors, p-values, and confidence intervals for the linear combination. These are based on the model, which adjusts for baseline differences, and therefore both groups have the same baseline score.

Results

Table 1 describes the baseline characteristics of the staff participants from 8 wards. Wards differed in terms of the number of participants and the range of grades represented.

Table 2 outlines the numbers of staff who participated at follow up, providing repeated measures. All repeat participants remained on the same ward throughout. By using unstructured multivariate linear models the figures shown below were augmented to N=120.

Did the DOORWAYS intervention (i.e. an experience of change) worsen how staff perceived barriers to change?

The repeated measures data revealed that staff perceptions of barriers to change grew comparatively worse over time in the intervention group. In the control group, there was little change. Notably, the intervention group also had more positive perceptions at the outset, and these remained more positive at follow up (figure 4), although the difference between the two groups was small.

Unstructured multivariate linear model exploring the potential negative effect of the intervention on staff perceptions of barriers to change, including covariates time, occupational status and ward

The impact of the intervention effect, time, occupational status and ward on VOCALISE were then tested in an unstructured multivariate model.

Overall this model was significant ($\chi^2(10) = 31.48; p > 0.001$).

Intervention effect

In this model, the constant is the predicted mean score at baseline, if study group = 0 (control) and time is 0 and occupational status = 0 (or 1 for ward). The constant is the same for both the control and intervention groups, because a zero treatment effect is enforced at baseline. This meets the assumption of an RCT that there is no difference between scores at baseline, because any actual difference is assumed to exist by chance.

Perceptions of barriers to change were significantly higher (and therefore more negative) in the intervention group than the control group at follow up, after adjusting for all other covariates. At follow up, the estimate for the intervention effect variable shows that the predicted mean score in the intervention group was 5.16 more than the predicted mean score in the control group.

This interpretation was not affected by reversing the coding. When the model was recoded to show the results for the control group, the adjusted change in score at follow up was significant (Coef. 5.16; S.E: 2.62; $p=0.05$; C.I: 0.02 to 10.30) and the control group had lower and more positive perceptions of barriers to change at follow up.

Time

There was a difference in the way that the two groups responded to change over time. There was evidence ($p=0.003$) of a change (adjusted for all other included covariates) in the estimated mean outcome score between baseline and follow up, in the intervention group. Over time, the scores in the intervention group became significantly worse because they increased by 5.39 points. The predicted mean outcome score in the intervention group at follow up was (75.20; C.I: 69.02 to 81.38). There was no significant change over time in the control group (Coef β : 0.23; S.E: 1.86; $p=0.90$; C.I: -3.42 to 3.89), if the model was rerun, changing the coding. The predicted mean outcome score in the control group at follow up was (70.04; C.I: 64.01 to 76.07), showing little change from the baseline score. This is consistent with figure 4, which shows that perceptions worsened in the intervention group and remained stable in control group.

Covariates

Occupational status significantly affected staff perceptions of barriers to change across time ($p=0.05$), after adjusting for all other predictors. Post hoc, the mean predicted perceptions of barriers to change for those in direct care positions were more negative than those in more senior positions (table 4).

The model does not explain whether the direct care staff perceptions of barriers to change were more negative as a result of participation in the intervention. However, adding an interaction between time and occupational status showed a significant effect at follow up, in both groups (Coef β : -7.62; S.E: 3.55; $p=0.03$; C.I:-14.59 to -0.65). Table 5 shows more negative change in the perceptions of direct care staff in the intervention group.

The estimate for ward shows that there was a direct effect of certain wards on the outcome across time. The staff on ward 1, which was the reference category and a control ward, had the most negative perceptions as indicated by the constant (69.81). There was a significant difference between the reference ward and wards 4 to 8, which shows that perceptions of barriers to change varied by ward.

The adjusted mean outcome scores were computed post hoc (table 6), which showed that perceptions on the intervention wards became more negative across time than those on the control wards.

Including an interaction between ward and time was not possible in the model because there were a limited number of participants per ward.

Discussion

Although the Nursing & Midwifery Council in the United Kingdom states that nursing staff should practice in line with the best available evidence (38), there is still a prominent disconnect between frontline practice and research evidence. Previous attempts to improve the uptake of research evidence into healthcare practice have generally targeted service users to adopt new interventions. This means that the role of ward staff in innovation has not been adequately investigated.

This study was part of an RCT (DOORWAYS) to improve the therapeutic milieu by delivering predominantly nurse led, CBT-based interventions. Although DOORWAYS had a positive impact on involuntary service user perceptions of, and satisfaction with, mental health wards (8), there were also negative side effects from the changes, as staff perceptions of barriers to change worsened in those who participated in the intervention group. This finding provides support for the theories of Lewin (19) and Schein (20), who suggested that change brings disruption that can create resistance amongst staff.

Given DOORWAYS was an externally devised change delivered in the form of a randomised controlled trial that was imposed at the ward level using a top down approach, it is perhaps unsurprising that staff responded negatively. This finding is in line with the wider management and health literature which shows that changes implemented using a top down approach, with little input from front line staff can produce negative outcomes of increased stress, reduced job satisfaction, reduced psychological well-being and lower motivation (39, 40).

However, DOORWAYS did involve nursing stakeholders, and many of the practical suggestions made by frontline staff were adopted at the implementation stage. Senior ward staff (but not frontline staff, who were expected to implement the changes) were involved in discussion about the project upfront. Feedback from frontline staff was incorporated into the strategy via the psychologist who helped staff to set up each wards groups and also provided training, support and leadership to staff to enhance the learning process. It may be, therefore, that these findings reflect insufficient front line staff involvement or the high levels of nursing input required by the DOORWAYS intervention, in addition to their other tasks,

with no time/resource allowance for that. As resources are limited in mental health wards, additional support may be required if complex RCTs are to be conducted in mental health wards in the future. Policy makers, National Health Service trusts and higher education settings might give further thought to how resources can be better allocated, given RCTs bring valuable learning experiences, which develop frontline staff, as well as measureable improvements and increased funding.

Although developing and implementing changes at the local level can produce more positive responses in frontline staff (41), these types of studies are rare. Future research programmes that seek to deliver substantial changes may need to develop implementations strategies which incorporate much greater stakeholder involvement, which could also be formally assessed over the period of change. This would also allow an exploration of whether more active stakeholder involvement might improve how staff regard barriers to change on the wards. In this way, feasibility issues might be addressed by encouraging staff generated adaptations that better suit the clinical environment.

Including contextual covariates in the model provided additional information to show that both occupational status and ward are involved in how staff respond to changes. In both groups, direct care staff had more negative perceptions of barriers to change than more senior staff. These findings are in line with previous literature (15-17, 21). In both groups, the estimated mean VOCALISE scores on each ward at T1 revealed that some wards had significantly different scores from the reference ward (ward 1, a control ward). Irrespective of group allocation, there were also staff with more positive perceptions of barriers to change, both at the outset and at follow-up. It may be that staff who are more optimistic at the outset, simply remain more positive throughout, which suggests that some staff are better at coping with changes than others.

The model was not able to explain whether the relationship between ward climate and participation in DOORWAYS resulted in a negative effect on perceptions of barriers to change. However, by including an interaction between occupational status and time, it was possible to show that the changes introduced by DOORWAYS had a more detrimental on direct care staff than managers, over the 12 moth time period. This finding extends the current literature, and suggests that future change programmes should be sensitive to those working in demanding, direct care roles, at the inception of change, and through the implementation phase, as this sub-group may need extra support.

Limitations & Research Implications

This study highlights negative side effects in terms of worsened perceptions of barriers to change as a result of a Trust-wide planned change, in a sample of mental health ward nurses. However, as only one

type of change was explored the results may not explain how ward staff might react to other types of innovation.

As this research was conducted in one trust, our understanding of the impact of DOORWAYS is restrictive. To ensure that future findings are widely generalizable, more than one organisation should be sampled. To better understand the impact of ward on perceptions of barriers to change, a larger number of wards should be included.

In implementation studies which are concerned with barriers in complex settings, the need to include contextual variables can mean that very large amounts of data are necessary to fully understand the picture. Although missing data were an initial problem in this study, unstructured multivariate linear models were used to overcome the reduced sample size. This method may therefore usefully inform future implementation studies.

Conclusions

This study showed that participation in a clinical trial (DOORWAYS), which represented a period of intense change, had a negative impact on mental health ward staff perceptions of barriers to change. Given the large and often stressful workloads of mental health ward staff, careful thought should be given to supportive change management strategies that take the perspective of these staff into account. Involving staff in the development of research initiatives early on, may help to reduce resistance later on. Research programmes should also consider including a flexible implementation strategy, which may be informed by ward staff, to assess the impact and reduce the burden of changes.

In addition, occupational status (being from the direct care group) worsened staff perceptions of barriers to change in both the intervention and control groups. However, those in the intervention group became more negative in their views of change across time, having participated in DOORWAYS. This suggests that staff who provide direct care should be offered extra support when changes are introduced.

Abbreviations

RCT: Randomised Controlled Trial

CBT: Cognitive Behavioural Therapy

Declarations

Ethics approval and consent to participate: A local NHS Research Ethics Committee (07/H0809/49) awarded ethical approval for this study.

Consent for publication: Not applicable.

Availability of data and material: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests

Funding: Professor Til Wykes, Professor Felicity Callard, Dr Matteo Cella and Dr Caroline Laker acknowledge the financial support of the NIHR Senior Investigator Award, The Biomedical Research Centre for Mental Health, South London and Maudsley NHS Foundation Trust and the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research scheme (RP-PG-0606-1050). We also acknowledge the support provided by statisticians (Dr Morven Leese and Paul Williams) from the Institute of Psychiatry, Psychology & Neuroscience, Department of Health Services and Population Research, King's College, London.

Authors' contributions

1. a) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work (CL, TW, MC).
2. b) Drafting the work or revising it critically for important intellectual content (CL, MC, FC, TW).
3. c) Final approval of the version to be published (CL, MC, FC, TW).
4. d) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (CL).

Acknowledgements: Professor Til Wykes, Professor Felicity Callard, Dr Matteo Cella and Dr Caroline Laker acknowledge the support provided by statisticians (Dr Morven Leese and Paul Williams) from the Institute of Psychiatry, Psychology & Neuroscience, Department of Health Services and Population Research, King's College, London.

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Tables

Table 1: Characteristics of the baseline participants.

Wards		1	2	3	4	5	6	7	8	Total (%)
N=	No. of staff	18 (15)	13 (10)	16 (12)	8 (6)	19 (15)	15 (12)	18 (15)	18 (15)	125 (100)
Staff Grade	HCA	7	3	6	1	5	4	7	6	39 (31)
	Band 5	8	7	7	3	12	8	7	6	58 (47)
	Band 6	1	2	1	3	1	0	3	4	15 (12)
	Band 7	1	1	1	1	1	1	1	1	8 (6)
	missing	1	0	1	0	0	2	0	1	5 (4)
Ethnic Group	White British /Other	6	2	3	4	5	3	4	6	33 (27)
	BME	12	11	12	4	14	12	14	10	89 (71)
	missing	0	0	1	0	0	0	0	2	3 (2)
Gender	Male	3	7	12	0	9	3	9	3	46 (37)
	Female	15	6	4	8	10	12	9	15	79 (63)
Age	Mean	39.63 (13.0)	36.38 (7.61)	38 (7.93)	44.25 (4.80)	43.26 (9.94)	35.38 (8.82)	39.6 (8.61)	40.07 (9.85)	39.57
	max/min	27-50	22-62	24-55	37-49	26-67	22-48	27-55	23-54	N/A

Table 2: The repeated measures sample numbers

Repeated measures sample									
Ward	1	2	3	4	5	6	7	8	Total (%)
Number of staff	4	10	3	3	12	3	9	10	54 (100)
Group (INT/CTL)	CTL	CTL	INT	INT	INT	CTL	CTL	INT	INT:28 (52) CTL:26 (48)

Table 3: Unstructured multivariate linear model (N=120, 8 wards) exploring whether participation in the intervention affected staff perceptions of barriers to change, adjusting for time, ward and occupational status

Variables			Coef. β	S.E.	P Value	95%C.I.	
						LL	UL
<i>Intervention effect</i>			-5.16	2.62	0.05	-10.30	-0.02
<i>Time</i>			5.39	1.84	0.003	1.78	9.00
<i>Ward</i>	CTRL	Ward 2	-0.45	3.83	0.91	-7.95	7.05
	INT	Ward 3	-6.31	3.72	0.09	-13.60	0.98
	INT	Ward 4	-11.12	4.57	0.01	-20.08	-2.16
	INT	Ward 5	-12.06	3.50	0.001	-18.91	-5.21
	CTRL	Ward 6	-9.67	3.88	0.01	-17.27	-2.07
	CTRL	Ward 7	-8.14	3.53	0.02	-15.07	-1.22
	INT	Ward 8	-7.48	3.64	0.04	-14.61	-0.35
<i>Occupational status: manager/direct care staff</i>			-4.91	2.45	0.04	-9.71	-0.11
<i>_cons</i>			69.81	2.56	0	64.79	74.83

Table 4: Predicted mean estimates for staff perceptions of barriers to change according to occupational status

Study group (95% C.I.)	Time	Direct care staff	Senior staff
Both groups	0	69.81 (64.79 to 74.83)	64.90 (58.36 to 71.44)
Control group	FU	70.04 (64.01 to 76.07)	65.13 (57.84 to 72.43)
Intervention group	FU	75.20 (69.02 to 81.38)	70.29 (62.78 to 77.81)

Note: FU=follow up.

Table 5: Predicted mean estimates for staff perceptions of barriers to change, including an interaction between time and occupational status

Study group (95% C.I.)	Time	Direct care staff	Senior staff
Both groups	0	69.77 (64.75 to 74.79)	65.40 (58.80 to 71.99)
Control group	FU	70.85 (64.66 to 77.03)	63.23 (55.08 to 71.37)
Intervention group	FU	75.85 (69.56 to 82.13)	68.23 (59.76 to 76.69)

Note: FU=follow up.

Table 6: Mean estimates for staff perceptions of barriers to change by ward

Ward	Estimated Mean VOCALISE score at T0 (95%C.I.)	Estimated Mean VOCALISE score at follow up (95%C.I.)
1 (CTRL)	69.81 (64.79 to 74.83)	70.04 (64.01 to 76.07)
2 (CTRL)	69.36 (63.62 to 75.10)	69.59 (63.32 to 75.86)
6 (CTRL)	60.14 (54.39 to 65.89)	60.37 (53.61 to 67.13)
7 (CTRL)	61.67 (56.73 to 66.60)	61.90 (56.14 to 67.65)
3 (INT)	<i>63.50 (58.15 to 68.86)</i>	<i>68.89 (62.59 to 75.19)</i>
4 (INT)	<i>58.69 (51.08 to 66.30)</i>	<i>64.08 (55.89 to 72.26)</i>
5 (INT)	<i>57.75 (53.00 to 62.50)</i>	<i>63.14 (57.61 to 68.68)</i>
8 (INT)	<i>62.33 (57.11 to 67.55)</i>	<i>67.72 (61.85 to 73.59)</i>

Figures

Ward	T0 (baseline)	T1 (6 months)	T2 (12 months)	T3 (18 months)	T4 (24 months)
3	Randomised	Intervention	Intervention	Intervention	Intervention
5	Randomised	Intervention	Intervention	Intervention	Intervention
4	Control	Randomised	Intervention	Intervention	Intervention
8	Control	Randomised	Intervention	Intervention	Intervention
1	Control	Control	Randomised	Intervention	Intervention
7	Control	Control	Randomised	Intervention	Intervention
2	Control	Control	Control	Randomised	Intervention
6	Control	Control	Control	Randomised	Intervention

Figure 1

The Stepped Wedge Randomization Procedure for DOORWAYS

Ward 3	Ward 4	Ward 5	Ward 8
Cognitive Remediation Therapy	Emotional Coping Skills	Cognitive Remediation Therapy	Cognitive Remediation Therapy
Social Cognition & Interaction Training	Problem Solving Skills	Problem Solving Skills	Problem Solving Skills
Hearing Voices		Hearing Voices	Hearing Voices
Relaxation Techniques			Emotional Coping Skills
Self Esteem & Coping with Stigma			

Figure 2

Training status at twelve months

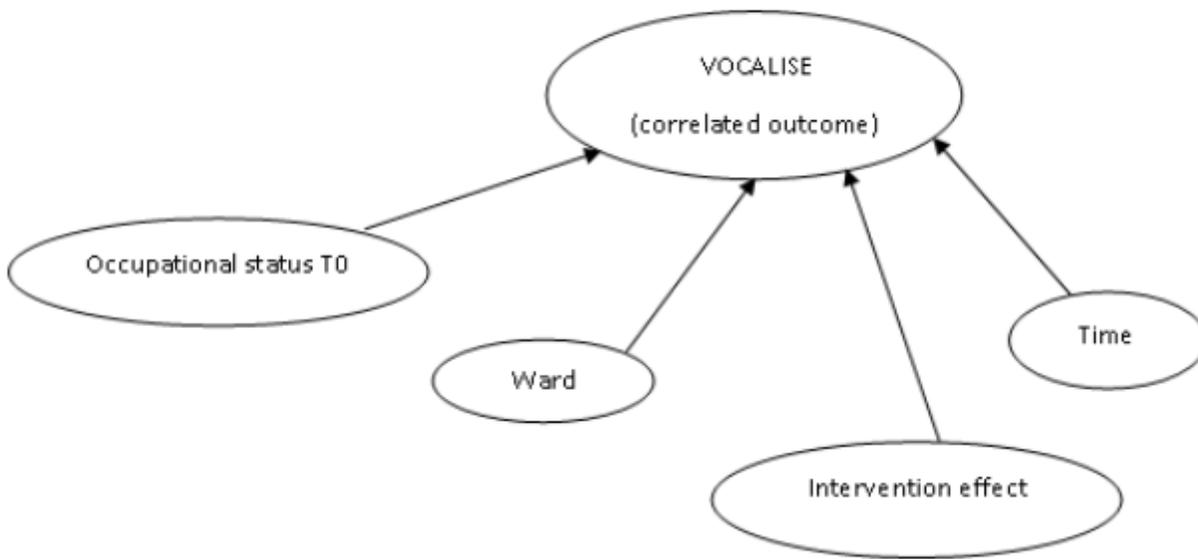


Figure 3

The potential negative intervention effect on staff perceptions of barriers to change when including covariates time, occupational status and ward.

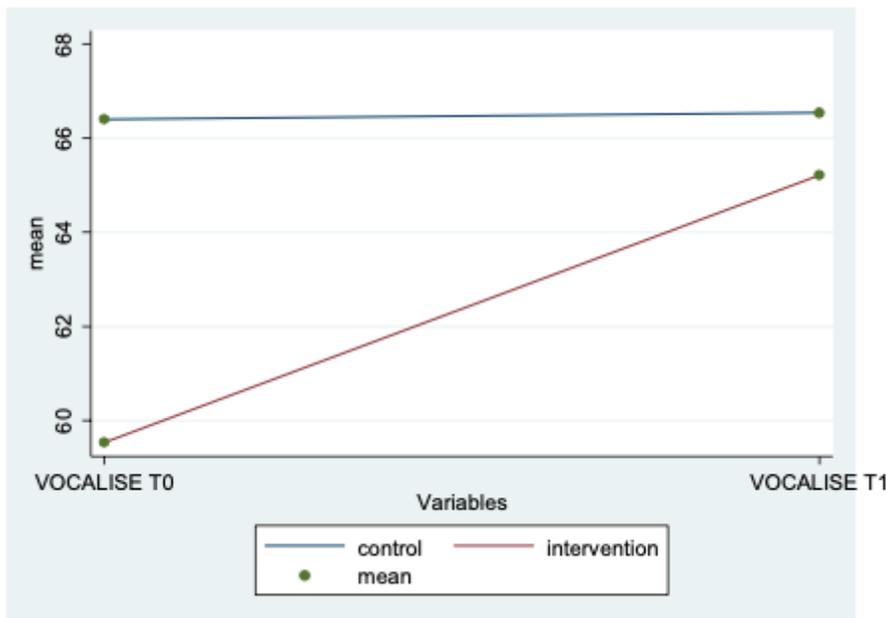


Figure 4

Raw Mean VOCALISE scores at T0 and follow up in the control and intervention groups (repeat participants)

Supplementary Files

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