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Title: Developing a theory-informed complex intervention to improve nurse-patient therapeutic engagement employing Experience-based Co-design and the Behaviour Change Wheel: an acute mental health ward case study.

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Word count: 5,371 – We have noticed that word counts in papers previously published by BMJ Open vary considerably, with some having up to 8,000 words. We recognise our paper is over the recommended 4,000 words, however we believe this is justified for the following reasons. First, this is a qualitative piece of work that aims to present both a new method for intervention development and systematically report a new intervention. To ensure the process is clear enough for others to replicate and also understand the mechanisms behind how the intervention works, it requires more than 4,000 words. Second, we currently have another paper under review, which reports in more detail the early stages of our process. To avoid salami slicing our work, we feel it is important that this part of our process is reported as one complete paper.

 Title: Developing a theory-informed complex intervention to improve nurse-patient therapeutic engagement employing Experience-based Co-design and the Behaviour Change Wheel: an acute mental health ward case study.

ABSTRACT

Objectives: Our objectives were threefold: 1) describe a collaborative, theoretically driven approach to co-designing complex interventions; 2) demonstrate the implementation of this approach to share learning with others and 3) develop a toolkit to enhance therapeutic engagement on acute mental health wards.

Design and participants: We describe a theory-driven approach to co-designing an intervention by adapting and integrating Experience-based Co-design (EBCD) with the Behaviour Change Wheel (BCW). Our case study was informed by the results of a systematic integrative review and guided by this integrated approach. We undertook 80 hours of non-participant observations, and semi-structured interviews with 14 service users (seven of which were filmed), two carers and 12 clinicians from the same acute ward. The facilitated intervention co-design process involved two feedback workshops, one joint co-design workshop and seven small co-design team meetings. Data analysis comprised the identification of touchpoints and use of the BCW and behaviour change technique taxonomy to inform intervention development.

Setting: This study was conducted over 12-months at an acute mental health organisation in England.

Results: The co-designed *Let's Talk* toolkit addressed four joint service user/clinician priorities for change: 1) improve communication with withdrawn people; 2) nurses to help service users help themselves; 3) nurses to feel confident when engaging with service users; 4) improving team relations and ward culture. Intervention functions included training, education, enablement, coercion and persuasion; 14 behaviour change techniques supported these functions. We detail how we implemented our integrated co-design/behaviour change approach with service users, carers and clinicians to develop a toolkit to improve nurse-patient therapeutic engagement.

Conclusions: Our theory-driven approach enhanced both EBCD and the BCW. It introduces a robust theoretical approach to guide intervention development within the co-design process and sets out how to meaningfully involve service users and other stakeholders when designing and implementing complex interventions.

Strengths and limitations of the study:

- To our knowledge, our study is the first to combine and implement a new theory-driven codesign/behaviour change process with service users, carers and clinicians in a mental health setting
- Our intervention development process was highly collaborative, with service users, carers and clinicians working together in equal and active partnership
- Our process provided a systematic and replicable system for reporting the behavioural mechanisms of action behind our complex intervention toolkit
- Although our process was highly collaborative, it was conducted at just one NHS site, which represents a possible limitation.

Background

Nurse-patient therapeutic engagement can broadly be described as the use of verbal and non-verbal interchange to improve a service users' mental health (1,2). Lack of high-quality engagement on acute mental health wards is strongly associated with increased rates of self-harm, violence, aggression, absconding and poor perceptions of inpatient care (3,4). Engagement may initiate and enhance the therapeutic relationship (5), which arguably has the greatest impact on treatment outcomes, over and above the specific interventions provided (6,7). However, nurses report high levels of acuity, reduced workforce, competing administrative duties and the nebulous nature of engagement as reasons for not engaging with service users (8,9,10). These factors also have a negative impact on nurses' job satisfaction (11), increasing the likelihood of burnout and leaving the profession prematurely.

Reports from service users suggest that wards are experienced as devoid from warm, respectful therapeutic interactions (12). Pharmacological treatments are prioritised over collaborative clinician-patient engagement, which leaves service users feeling stigmatised and alienated from their care team (13,14). Despite a recognition of the importance of collaborative care planning by clinicians, service users were often not involved in this process and felt as if they had no say in the trajectory of their care (15). Policymakers, researchers and patient advocacy groups globally have emphasised the importance of engagement in practice (16,17,18). However, lack of quality engagement is a longstanding, complex problem (19,20) and few nursing interventions to improve engagement are reported in the literature.

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One such intervention, predominantly implemented in the United Kingdom (UK) is Protected Engagement Time (PET). During PET, nurses devote a specified amount of time to regular engagement sessions with service users (21,22). PET originates from the Refocusing Model, which was a comprehensive series of interventions to improve inpatient services and reduce work strain on staff (23,24). The Refocus Model brought about improvements to the quality of care, staff sickness and costs, rates of absconding and self-harm (23). Following this, PET was adopted as a standalone intervention by mainstream policy (e.g.25), which resulted in its top-down implementation in many mental health services across England. Subsequent evaluations on both adult and older adult mental health wards found that whilst PET attempts to address nurses' opportunities to engage, it does not account for wider considerations about what is done within the engagement sessions (26,27,28). This may be because PET was intended to be used alongside other interventions, and its use as a standalone intervention stemmed from an atheoretical, common sense approach to implementation.

In response to PET's limitations, a Swedish study developed the Time to Talk (TT) intervention (29). TT is a form of PET, theoretically informed by two studies of everyday life on acute wards (30,31) and the Tidal Model – a holistic model of nursing care that promotes the exploration of service users' own narratives (32). In a qualitative evaluation of TT (33) service users reported that clinicians were more engaged after TT was implemented; however, their quantitative evaluation found no improvement in the quality of engagement as measured through the Caring Professional Scale (34). This mirrors evaluations of PET (26,27). Although PET and TT address nurses' opportunities to engage, they may not compensate for wider deficiencies in service provision such as poor supervision, clinical skills, and personal motivations (26,28), and neither were collaboratively developed with input from service users, carers and clinicians.

To better understand and enhance nurse-patient engagement in practice we previously conducted a systematic integrative review to develop a conceptual model of engagement (35). For high quality engagement to occur, the model suggests that nurses must employ techniques that encompass five "Principles of Engagement": 1) understand the person and their illness; 2) facilitate growth; 3) therapeutic use of self; 4) choose the right approach and, 5) emotional versus restrictive containment. The model drew upon behaviour change theory (36) to show that engagement is broadly influenced by both the service users' and nurses' capability, opportunity and motivation to engage. To address the limitations of previous interventions, we propose a collaborative, theory-driven approach to co-designing a complex intervention to improve the amount and quality of engagement on acute mental health wards. To do so, we have drawn from our model of

engagement described above and adapted and integrated two existing approaches: Experiencebased Co-design (EBCD) (37,38) and the Behaviour Change Wheel (BCW) (36).

EBCD is a form of participatory action research which draws on user-centred design and user experience to improve healthcare services (37). The structured EBCD process, detailed in a freely available online toolkit (39), aims to meaningfully engage service users, carers and clinicians throughout a co-design process using observations, interviews and facilitated workshops. The Behaviour Change Wheel (BCW) and accompanying Behaviour Change Technique Taxonomy (BCTTv1) has amalgamated 19 behaviour change theories to create a framework that guides intervention development (36). It follows three phases: 1) understand the behaviour; 2) identify intervention options and 3) identify intervention content. At its core, the model suggests that capability, opportunity and motivation interact to create behaviours (COM-B) (40). The Theoretical Domains Framework (TDF) (41) is aligned in the model to the COM-B components and both are linked to nine intervention functions. The BCTTv1 is a taxonomy of 93 behaviour change techniques (BCTs). These 93 BCTs can be matched to the intervention functions to identify suitable behaviour change techniques (BCTs), which make up the active ingredients of an intervention (42,43). Figure 1 maps the BCW phases, methods and tools to the phases, methods and tools of EBCD and provides a theory-driven basis for the co-design of behaviour change interventions.

Figure 1 – Integrated Co-design – Behaviour Change model

Healthcare research and policy now recognise the importance of both co-designing interventions and using a robust theory to guide intervention development (44,45), but to date very few studies report on how to co-design complex healthcare interventions using a theory-driven approach. Currently there are no published studies that develop interventions using EBCD informed by the BCW. In response, we demonstrate the implementation of a theory-driven co-design-behaviour change process (Figure 1) that was used to develop a complex intervention toolkit for promoting nurse-patient engagement on acute mental health wards. We aim to:

- Describe a collaborative, theoretically driven approach to co-designing complex interventions;
- Demonstrate the implementation of this process to share learning with others;
- Develop a toolkit to enhance therapeutic engagement on acute mental health wards.

Methods

Design

This case study was guided by the UK Medical Research Council (MRC) complex intervention framework (46) and was theoretically driven by the content illustrated in Figure 1. The co-design process is reported in accordance with guidance for the reporting of intervention development studies in health research (GUIDED) (47) (Supplementary file 1). Ethical approval for the study was obtained from the London Fulham Research Ethics Committee (reference: 18/LO/2193). Participants gave written consent prior to being interviewed and again at the start of each co-design workshop. Posters that explained the purpose of the ward observations were displayed in common areas on the ward. Participation in observations was on an opt-out basis, to which nobody opted out.

Setting

The study was conducted with service users, carers and clinicians from one inner-London National Health Service (NHS) Foundation Trust in England, where the lead author had previously conducted exploratory work (5). The intervention ward has 18 beds and treats adults (18-65) experiencing an acute phase of severe mental illness. The ward is laid out along a corridor, with the nursing station and reception area at one end of the ward, the service user bedrooms running along both sides of the corridor and the service user lounge and day area at the opposite end of the ward to the nursing station. Service users are predominantly detained under the Mental Health Act (48). The ward consists of a multidisciplinary team of 20 clinicians, including eight registered mental health nurses (RMNs), seven health care assistants (HCAs), a peer support worker, an activities coordinator, an occupational therapist, a psychologist and a consultant psychiatrist. The nursing team works shift patterns from 0730-2130 or 2100-0800 and all RMNs and HCAs are involved in direct patient care including care planning, one-to-one interactions, close and hourly observations. The RMNs are responsible for medication rounds. The ward provides timetabled daily activities, run by the activities coordinator and service users attend weekly ward rounds led by the consultant psychiatrist and an RMN. This project began in April 2018 and complemented other organisational improvement work to re-implement PET.

Participants

The co-design team was recruited through:

- A convenience sample of service users and carers via: 1) face-to-face contact and posters at community mental health teams (CMHTs) and 2) face-to-face contact and email at service user advocacy groups connected to the participating NHS organisation;
- A whole population sample of clinicians on the participating ward were invited to take part via presentations, posters, email, and face-to-face meetings.

SM screened all potential participants, specifically looking for those who had, or had cared for somebody who had at least one inpatient admission at the organisation but was not currently experiencing a relapse. Eligible individuals were then guided through a written informed consent procedure. Figure 2 shows the recruitment process by type of participant and workshop attendance through the EBCD process. A total of 35 members were recruited to the co-design team including 15 service users, two carers, 10 RMNs, four HCAs, three psychological therapies clinicians and one student nurse. Just over half of the co-design team were female (54%) and just under half were from a Black, Asian and minority ethnic background (49%). Participants' ages ranged from 18-64 years. Service users had a variety of mental illnesses, including psychotic disorders such as schizophrenia and bipolar affective disorder (71%), personality disorder (7%), anxiety (7%) and eating disorder (7%).

Figure 2 – Recruitment process by type of participant and workshop attendance

Data collection and analysis

Data collection methods and processes were aligned to the EBCD phases and BCW stages contained in Figure 1 and informed by the aforementioned integrative review (35) these included nonparticipant observations and semi-structured interviews to gather service user, carer and clinician experiences, and feedback and co-design workshops to facilitate development of the engagement toolkit.

Non-participant observations and semi-structured interviews

SM (a mental health nurse, previously unknown to the study participants and trained in the application of the EBCD and BCW approach) conducted 80 hours of non-participant observations on the acute ward between the hours of 0730-1500 or 1330-2130, Monday through Sunday. Observations were performed in 15-minute intervals, beginning with the first nurse encountered

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and continued until all nursing staff had been observed. Fieldnotes were guided by Tyson and colleagues (49) and documented patterns of nurse-patient behaviour, nurse-patient dynamics, tone of voice, body language, potential influences on engagement and general ward atmosphere.

SM also interviewed 14 service users, two carers and 12 clinicians on a one-to-one basis at a location of their choice including university premises, offices at CMHTs or by telephone. All interviews were audio recorded and seven service user interviews were filmed in keeping with the EBCD approach. Interviews lasted between 30-80 minutes. A topic guide was followed, informed by our review (35), the non-participant observations and the COM-B/TDF domains (41,42). Interviews addressed participants' experiences of engagement, barriers and facilitators to engagement, and clarified assumptions made from the observations.

Full details of the non-participant observations and semi-structured interviews, including the inductive analysis of data to identify 'touchpoints' (emotionally significant points) of importance to the co-design team, are reported in a separate paper (50). A secondary deductive analysis of interview data, which is reported in this paper, was also undertaken to identify barriers to engagement. Deductive codes were based on the COM-B and TDF components of the BCW which were used as an *a priori* framework to analyse and thematically organise interview data. SM independently coded and themed the data using this framework. Extracts from both the filmed and audio-recorded interviews were also edited into a trigger film that was used to stimulate discussion at the feedback and co-design workshops.

Feedback and co-design workshops

Touchpoints and themes were shared at separate service user/carer and clinician feedback workshops and at a joint co-design team workshop. This ensured validity of the analysis, facilitated the joint selection of target behaviours based on the touchpoints, and allowed intervention options and content to be agreed. Seven co-design team meetings were also established to work on specific priority areas. Consensus was reached through facilitated discussions and consensus building exercises including emotional mapping (51) and affinity grouping (52).

Input was also sought throughout the co-design process from two mental health patient and public involvement (PPI) groups based at the participating organisation. An advisory group consisted of a service user representative, one clinician and clinical academic experts in (a) the EBCD methodology and (b) therapeutic engagement, respectively. The service user representative co-facilitated the feedback workshops with SM who also facilitated the joint co-design and co-design team workshops with the assistance of another nurse researcher trained in the BCW approach. Three co-design team

members wrote reflective accounts of their experiences of the co-design process and are co-authors of this paper.

Patient and public involvement

Service users and carers were at the heart of this research, being involved from conception, through execution and dissemination of this work.

Results

Here we present our theory-driven approach to co-designing the *Let's Talk* complex intervention toolkit. Our findings are organised under the three stages (and eight constituent steps) of the BCW guide, as shown in Figure 1.

Stage 1: Understanding the behaviours

Step 1: Define the problem in behavioural terms

Through previous research (5), our integrative review (35) and initial discussions with our PPI, advisory groups and the clinical service lead, modern matron and divisional medical director at the NHS organisation, the behavioural problem was defined as the absence of high-quality nurse-patient therapeutic engagement on acute mental health wards i.e. not using the Principles of Engagement identified in our review.

Step 2: Select target behaviour(s)

In keeping with the EBCD methodology, it was important to understand how service users and staff typically experienced engagement prior to the identification of relevant areas for behavioural change. Through observations and semi-structured interviews, the research team identified 28 touchpoints. Some examples of touchpoints were 1) I was left on my own and ignored; 2) my care was robotic and 3) As a nursing team we need to create better bonds with service users (full results in preparation to be published elsewhere).

 To ensure credibility, the touchpoints were discussed during two facilitated feedback workshops – one for service users and one for clinicians. In an emotional mapping exercise, participants were encouraged to identify improvement priorities based on their touchpoints and assign associated behaviours (see supplementary file 2 for breakdown of touchpoints into improvement priorities and associated behaviours). Participants then ranked their improvement priorities in a dot voting exercise and chose four priorities to take forward to the joint workshop (Table 1). The service user and clinician priorities were as follows:

Service user priorities	Clinician priorities		
1) Nurse-patient communication needs to be	1) Improve the way we communicate with		
improved	service users		
2) Treat me like a human being	2) Improve the way that leave is communicated		
3) Forgive and forget	3) Improve culture around response		
4) Help me help myself	4) Improve the way messages are handed over within the team		

At the joint workshop, facilitated discussion encouraged participants to consider the potential impact, likelihood of change, spill over effect and ease of measurement of all the improvement priorities and associated behaviours. An affinity grouping exercise was conducted and through this, four shared improvement priorities were identified and agreed:

- 1) Improve communication with withdrawn people
- 2) Nurses to help service users help themselves
- 3) Increasing nurses' confidence when interacting with service users
- 4) Improve team relations and ward culture.

Step 3: Specify target behaviour(s)

EBCD focuses on identifying participants' improvement priorities as a way of bringing about change that is meaningful to service users and clinicians (39). We used the BCW to examine each of the four

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joint improvement priorities. At the joint workshop, the co-design team formed into smaller groups with equal numbers of service users and clinicians. Each group completed a written exercise where they examined the joint priorities and associated behaviours in terms of who needs to perform the behaviour, what the person needs to do differently to achieve change and when, where, and with whom they will do it (Table 2) (See supplementary file 3 for example of written exercise).

Table 2 – Specification of behaviours for joint improvement priorities	

Joint improvement	Behaviour specification					
priorities	What	Who	Where	When/with whom		
Improve communication	1) Recognise who needs to engage	Nurses	Acute ward	When service users		
with withdrawn people	2) respond in a timely and appropriate			require		
	manner when engaging			engagement		
Nurses to help service	1) Give practical advice 2) explain the	Nurses	Acute ward	During service		
users help themselves	purpose of admission 3) understand the			user's admission to		
	person 4) facilitate growth 5) give			an acute ward		
	discharge support					
Nurses must feel	1) Have effective therapeutic	Nurses	Acute ward	When engaging		
confident when engaging	conversations 2) articulate practical			with a service user		
with service users	procedures in an understandable way					
	3) reduce anxiety when engaging					
Improving team relations	1) Ensure nursing team take care of each	Nursing	Acute ward	Throughout their		
and ward culture	other 2) understand nurse-patient	team		shift with the		
	dynamics on the ward 3) ensure a			nursing team and		
	consistent response to service users			with service users		

Step 4: Identify what needs to change

From our review and semi-structured interviews with service users, carers and clinicians, the research team identified 26 barriers to engagement and mapped them to the COM-B/TDF domains. The barriers were discussed with participants at the feedback workshops to ensure credibility. At the joint workshop participants matched the barriers to their four joint improvement priorities. The barriers related to each COM-B component are discussed below, with the corresponding TDF domains presented in parentheses.

Capability

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Participants agreed that nurses often had limited knowledge and inadequate training in therapeutic engagement techniques (skills and knowledge):

"Although I've been doing this for almost five years it's like sometimes with certain patients you just don't know what to say...I wish there could be some training to understand that stuff." – RMN6

Nurses also felt that the very nature of having a mental health problem could make it difficult to engage, and while service users agreed that their mental illness and medication effects could negatively impact engagement (memory/attention/decision process), they were able to describe helpful engagement techniques that nurses could employ, even with the most acutely unwell people. This further highlighted the need to improve nurses' engagement skills:

"Sometimes you have a lot more patients who are unwell or sometimes they're less unwell, so engagement fluctuates week on week from that point of view" – RMN2

Opportunity

It was felt that there needed to be a cultural shift on the ward and within the organisation so that nurse-patient engagement activities were supported and valued in the same way as other tasks such as hourly observations or administrative duties (social influences):

"It was a numbers game, everyone's taking handover, another one's doing checks, some are on break...in an ideal world allocate friendly HCAs just to sit with patients." – SU7

There was unanimous agreement that lack of resources negatively impacted on nurses' ability to engage therapeutically:

"The problem for me lies on the number of staff, that is not enough..." – C1.

This created an untherapeutic ward environment where *"professionals would run around like mad rabbits not giving any attention to the patients."* – SU2 (environmental contexts and resources).

Motivation

Nurses felt that they could not always trust all members of their team to carry out the job in the right way. This created a feeling of helplessness for some nurses, which deterred them from engaging therapeutically (beliefs about capabilities):

"I became very aware that when there is an incident, I'm left on my own...I stopped trusting the team...I couldn't rely, therefore I needed to take a step back from the patients." – HCA2

Service users were also deterred from approaching nurses for engagement because they felt nurses often did not understand their problems or would punish them if they asked for therapeutic engagement too often (beliefs about consequences):

"I kept myself to myself because even when I asked for simplest of things I was made to wait for ages so I would get frustrated, but if I showed frustration no doubt that would be on my notes and I would get set back." – SU4

As well as issues of trust, the ward staff felt as though their team were transient, with many longstanding nurses leaving to work elsewhere. This led to a lack of shared responsibility. Therapeutic engagement could easily *"fall through the cracks* – HCA1" and when poor quality engagement was witnessed, it was rarely followed up by a senior member of the team. This made some nurses feel they could not be bothered to engage:

"I mean to put it blunt; I know it sounds really bad...I can't be bothered." – RMN5

There was also a blurring of professional roles, where although nurses knew they should engage, they left it to other professionals such as the occupational therapist or activities coordinator:

"I can completely understand why nurses want separate roles because they would say you don't do our job so why should we do yours, but I do take people out on escorts and I do blur the boundaries there." – PT1.

When asked to give examples of nurse-patient engagement, many service users spoke about engagement with professionals other than nurses. This shows both the lack of engagement from nurses and the difficulty service users have in delineating between the nursing role and the role of other health professionals (social/professional identity).

There was a general sense from nurses that therapeutic engagement "didn't always help people" – RMN8 (optimism). This led some nurses to feel anxious about engaging therapeutically, particularly when they felt they did not have the required skills. When this was coupled with feelings of frustration at the perceived lack of managerial support, nurses reported feeling drained, burnt out and demotivated (emotions):

"One of the biggest problems is the management style which on paper, yes, it seems to be doing everything right, but in practice they have a very poor relationship with their staff and that does impact on performance...I just feel like no one cares about you, so why give up your time?" – RMN3

Stage 2: Identify intervention options

Step 5: Identify intervention functions

PPI and advisory group meetings highlighted that some of the terminology used to describe intervention functions would not be suitable to use with our participants. Words such as "coercion" can have negative connotations to mental health service users. Instead, practical examples that captured the essence of each intervention function were provided to participants at the joint codesign workshop. In a written exercise they were encouraged to use these examples to think about intervention functions that could address their four joint improvement priorities. Where possible we modelled these examples on illustrations from interviews with service users and staff. Where this was not possible, we developed examples from the BCW book (36) (Table 3).

Intervention function	Practical example given to co-design team
Education (Increase knowledge or understanding)	Service users meet with nursing staff once they have recovered and describe their experiences whilst on the ward *
Persuasion (Using communication to induce positive or	Have a poster on the ward that shows people happily engaging,
negative feelings or stimulate action)	with a message that reminds clinicians that engagement is part of their job, it is not "slacking off" *
Incentivisation (Create an expectation of reward)	Offer a prize for the ward that has the best patient feedback regarding interactions ^
Coercion (Create an expectation of punishment or cost)	At discharge, ask service users to provide feedback to the ward about the quality of interactions provided and hold staff accountable for this *
Training (Imparting skills)	Training program that enables nurses to role play with service users, so they gain skills on how to deal with service users' problems *
Restriction (Using rules to reduce/increase the opportunity to engage in target behaviour)	Nurses stop paperwork/admin during mealtimes and sit with service users and have a cup of tea or some food *
Environmental restructuring (Changing physical or social context)	Give service users cards that display different emotions and if the want to talk they can put the card on their door so nurses know to approach them *

Table 3 – Practical examples o	f behaviour change wheel functions given to co-design team

Modelling (Providing an example for people to aspire to or	Have a therapeutic engagement champion who promotes
imitate)	engagement and helps nurses to carry out group activities with
	patients *
Enablement (Increasing means or reducing barriers to	Have a ward diary for interactions that a member of staff is
(
increase capability beyond environmental restructuring)	responsible for each shift *
	I

Key: * = example that came from participant interviews; ^ = example developed from BCW guide

Participants identified five intervention functions that were relevant to bringing about the desired change. These were 1) training; 2) education; 3) enablement; 4) coercion and 5) persuasion. Through discussions with senior management, the research team also identified restriction as a relevant function. The links between the COM-B/TDF domains and the intervention functions are shown in Table 4.

Step 6: Identify policy categories

The BCW includes policy categories which may help to support the delivery of an intervention. Through discussion with senior management, the research team identified communication/ marketing, guidelines and social planning as potentially relevant to facilitating our intervention. As such, the Principles of Engagement described in the introduction of this paper were included within Trust policy on therapeutic engagement and observations, and these principles will be directly linked with other components of the intervention, such as a training film described below.

Stage 3: Identifying intervention content and implementation options

Step 7 & 8: Identify behaviour change techniques and mode of delivery

Rather than provide participants with a long list of BCTs, the written exercise at the joint workshop encouraged them to design intervention strategies they thought relevant to each of the four priorities and its influencing factors. The research team retrospectively assigned BCTs to the participants' examples and selected further BCTs and intervention strategies not identified during the joint workshop. These were the basis for the development of the first intervention prototype.

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The prototype was further refined through an iterative process of email exchanges, telephone calls, a PPI meeting, seven small co-design team meetings and finally presentation of the work at an organisation wide acute care forum. As per the BCW guide (36) the APEASE criteria (affordability, practicability, effectiveness/cost effectiveness, acceptability, side effects/safety and equity) were used in an adapted form (see supplementary file 4) to stimulate discussion and ideas. These criteria ultimately informed the choice of intervention strategies for each improvement priority.

Fourteen BCTs were considered relevant to the *Let's Talk* intervention toolkit. Table 4 shows the link between each phase of the behaviour change intervention design process, the 14 BCTs and the intervention strategies and modes of delivery which resulted from the co-design process.

The *Let's Talk* toolkit consisted of four main components, linked to the co-design team's four joint improvement priorities:

- A 30-minute training film for nurses, delivered by service users and carers to be shown to nurses at the start of the intervention. Service users and carers discuss good and bad engagement techniques and personal accounts of their experiences of engagement whilst an inpatient, structured by our model of engagement.
- 2) An illustrated workbook called *My Conversation Companion* which includes guided exercises that nurses and service users can do together to help structure therapeutic conversations.
- 3) Signs attached to the outside of service users' bedroom doors to enable them to indicate, with a sliding panel, whether they would like engagement time or not. The signs are linked to the hourly nursing observation record, where each hour nurses will be required to record if a service user has requested engagement and if that request has been fulfilled. "Missed engagement" will be handed over at each nursing shift with the expectation that it is fulfilled that day. Observation records will be audited each month and feedback given to the nursing team. Additionally, an illustrated sign on the inside of service users' doors will encourage service users to use the signs if they want to engage.
- 4) Changes to nurses' daily routines, for example during handover, time will be made to checkin with the nursing team and offer additional support to any team member that needs it that day. Additionally, quarterly facilitated workshops will bring clinicians and service users together to discuss, reflect and improve practice.

Whilst conducting this work, the organisation was simultaneously discussing the potential addition of one extra staff member per shift. Our co-design team felt this would be beneficial to improving therapeutic engagement, however a decision on this is yet to be made. Through discussions with the chief nurse, assistant director of nursing and divisional medical director and presentation of the work at an acute care forum it was agreed that the *Let's Talk* intervention would support the relaunched implementation of PET within the organisation. Discussion with participants revealed that they supported this and considered some form of PET essential to support nurses to use *Let's Talk* in practice. See Supplementary file 5 and 6 for the toolkit.

Table 4 – The behaviour change intervention co-design process and components of the resultingLet's Talk intervention toolkit

Behavioura	I analysis using COM-B/TDF	Intervention	BCTs	Intervention strategies/mode of delivery			
(step 4)		functions (step 7)	(step 8)				
		(step 5)					
Priority 1: Improve communication with withdrawn people							
	Knowledge:		\mathbf{N}				
	- Nurses think service users	Education	Prompts/cues	Prompt/cues: Sliding door signs & accompanying			
	who stay in their rooms do			supportive informational message on inside of service			
	not want to interact			users' door – acts as a cue for nurses to easily identify			
				service users who wanted to engage despite isolating i			
				their bedrooms. Acts as a cue for service users to			
CAPABILITY				encourage them to ask for engagement if needed			
	Memory, attention,						
	decision:	Education	Prompts/cues	Prompt/cues: as above			
	- Service users' illness can						
	make it difficult to engage /						
	lose touch with reality						
	- Medications can make it	N/A	N/A	Addressed in priority 3			
	difficult to interact / retain			Addressed in priority 5			
	information						
	Social influences:	Destriction	Fredericate				
	- Nurses must do	Restriction	Enablement:	Action planning: hourly observation record – each hou			
	observations within a set	Enablement	Action planning	allocated observation nurse records which service use			
	period, so focus on getting			door sign signals an engagement request and whether			
	the task done rather than			that request has been met. If request not met			
	speaking to the service			immediately, the observation sheet prompts nurse to			
	users			plan with the service user about when engagement wi			
				happen.			

Behavioural	analysis using COM-B/TDF	Intervention	BCTs	Intervention strategies/mode of delivery
	(step 4)	functions	(step 7)	(step 8)
		(step 5)		
OPPORTUNITY	Environmental context and			
	resources:			
	- Nurses feel they do not	Restriction	Restriction:	Restrictions & restructuring the social environment:
	have the time to	Enablement	Currently no BCTs for this	Protected Engagement Time – requiring nurses to stop
	interact/are allocated too		function	duties that do not involve engagement for one hour e
	many patients to interact		Enablement:	day and use that hour to engage. This supports nurse
	with all in one shift		Restructuring the social	use the Let's Talk toolkit with service users
			environment	
	- Nurses are busy so it is	Environmental	Environmental restructuring:	Prompts and cues: Sliding door signs & accompanying
	easy to miss service users	restructuring	Prompts / cues	supportive informational message on inside of service
	who are quiet			users' door – as above
	Beliefs about capabilities:			
	- Nurses feel helpless	N/A	N/A	Addressed in priority 2 & 4
	- Service users feel the	N/A	N/A	Intervention did not address this directly as it was
	nurses will not understand			thought that if nurses' behaviour changes and
	them if they talk to them		0	engagement is improved, this barrier will be mitigated
	Beliefs about			
	consequences:			
	- Nurses cannot be	Coercion	Coercion: Discrepancy between	Discrepancy between current behaviour and goal,
	bothered to interact as they	Education	current behaviour and goal	feedback on behaviour: hourly observation record –
	feel other tasks take		Education: Feedback on	Nursing team set goal of meeting all engagement
	precedence over		behaviour	requests each day. Allocated observation nurse recor
	interactions			levels of engagement each hour. Levels of "missed
				engagement" fed back to nursing team via monthly au
MOTIVATION				and compared to set goal daily during nursing handov
				Prompt/cues: Supportive informational message insid
	- Service users are fearful of	Education	Education: Prompts/cues	service users' door - acts as a cue for service users to
	initiating an interaction			encourage them to ask for engagement if needed
	Social/professional			
	identity:			
	- Transient team so no	Education	Self-monitoring of behaviour	Self-monitoring of behaviour: hourly observation reco
	sense of shared			- nurse in charge to check & record unmet engageme
	responsibility			requests and handover to next nursing team. Enables
				nursing team to monitor behaviour and create
				accountability within the team
	Emotion:			
	- Nurses feel anxious about	Enablement	Enablement:	Enablement: Adding objects to the environment: Slidir
	approaching a person who		Adding objects to the	door signs – shows nurses that people who are in their
	stays in their room		environment	rooms want to engage
Priority 2: Nu	rses to help service users	help themselv	es	·
CAPABILITY				

2 3 4 5	Behavioural a	analysis using COM-B/TDF (step 4)	Intervention functions	BCTs (step 7)	Intervention strategies/mode of delivery (step 8)
6 7 8 9 10 11 12		- Nurses say they are unsure what to say to service users when they are unwell or have big problems	(step 5) Training	Instruction on how to perform the behaviour	Instruction on how to perform the behaviour: My Conversation Companion workbook – provides nurses with short, guided exercises that can be done with service users. This helps structure therapeutic conversations. This is supported further by priority 3
 13 14 15 16 17 18 19 20 21 	OPPORTUNITY	Environmental context and resources: - The overall ward environment is not set up for quality interactions with service users	Restriction Enablement	Restriction & enablement: Restructuring the social environment	Restrictions & restructuring the social environment: <i>Protected Engagement Time</i> – requiring nurses to stop duties that do not involve engagement for one hour each day and use that hour to engage. This will support nurses to use the Conversation Companion with service users
 21 22 23 24 25 26 27 28 		 Nurses feel they do not have the time for quality interactions / allocated too many patients to interact with all on one shift Beliefs about capabilities: 	R		
29 30 31 32 33 34 35		- Nurses feel helpless	Education	Education: prompts/cues	Prompts and cues: My Conversation Companion workbook – prompts nurses' therapeutic conversations by providing short, guided exercises to complete with service users e.g. working through service users' stressors or helping a service user identify their feelings from an emotions table
 36 37 38 39 40 41 42 43 		Social/professional identity: - Blurring of professional roles e.g. OTs & activities coordinators do activities groups, not nurses	Education	Education: reattribution	Reattribution : <i>My conversation companion workbook</i> – encourages nurses to engage with service users and reattribute this work as being part of their role
44 45 46 47 48 49 50	MOTIVATION	Optimism: - Nurses feel that they make an effort with service users, but it is not remembered or appreciated	N/A	N/A	Addressed in priority 3
51 52 53 54 55		- Nurses feel that engaging is not always an effective intervention for some service users Emotion:	N/A	N/A	Addressed in priority 3
56 57 58 59 60		- Nurses feel anxious about approaching a person when	Enablement	Enablement: Adding objects to the environment	Adding objects to the environment – My Conversation Companion workbook – provided to the ward to facilitate

Behavioura	l analysis using COM-B/TDF	Intervention functions	BCTs	Intervention strategies/mode of delivery
	(step 4)	(step 5)	(step 7)	(step 8)
	they are not sure what to			engagement between service users and nurses to help
	say to them			structure and guide therapeutic conversation
Priority 3: N	urses must feel confident v	vhen engaging	; with service users	
	Skills:			
	- Nurses do not have the	Training	Training: Instruction on how to	Instruction on how to perform the behaviour: Trainin
	skills or knowledge to deal	Education	perform the behaviour, feedback	film shown to nurses – our review identified five
	with service users'		on the behaviour, feedback on	principles for engagement, these are used in the film
	problems		the outcome of the behaviour	educate nurses on how therapeutic engagement shou
				be carried out in practice. Each principle is illustrated
	- Nurses say they are unsure		Education: Information about	through a video clip from the participant interviews
	what to say to service users		health consequences	giving personal examples of the techniques nurses use
	when they are unwell or			with them to fulfil each principle of engagement
	have big problems			
				Feedback on behaviour & outcomes of behaviour:
				Training film – the co-design team discussed the
				outcomes of both the lack of engagement and when
CAPABILITY				good engagement occurred e.g. "I think some nurses j
				see it as a nine to fivethey just want to get home and
				have dinner, you know? But considering how sick I we
			6.	that lack of interaction made me feel very frightened."
			e le le	SU8
			4	Information about health consequences: Training film
				Service users and carers discuss the mental health
				consequences of lack of engagement & good
				engagement e.g. "I felt like I wasn't being looked afte
				the nurses so I had to do silly things like I overdosed or
				tablets, I kept abscondingthere were a lot of problem
				associated with my illness the nurses didn't recognise.
				SU2
	Memory, attention,			
	decision:			
	- Service users' illness can	Training	Training: Instruction on how to	Instruction on how to perform the behaviour: <i>Trainin</i>
	make it difficult to engage /		perform the behaviour	film – service users and carers discuss how nurses can
	lose touch with reality			engage despite illness and medication side effects e.g
				you just learn to listen, that's quite often all somebody
	- Medications can make it			wants, but what nurses are trying to do is fix it and it
	difficult to interact / retain			doesn't need fixing, it just needs to be heard by the
	information			staffthey need to hear what that patient is going
				through and why they want to do what they want to a
				Whether that's self-harm, suicide, a delusional belief,

Behavioural analysis using COM-B/TDF (step 4)		Intervention BCTs functions (step 7) (step 5)	Intervention strategies/mode of delivery (step 8)	
				whatever it is they need to understand that's a mental disorder that needs the help and support from the nurses" – SU11
OPPORTUNITY	Environmental context and resources: - Nurses feel they do not have the time to interact/ are allocated too many patients to interact with all in one shift	Training	Training: Instruction on how to perform the behaviour	Instruction on how to perform the behaviour: Trainin film – service users and carers discuss how engagemen does not need to be a long, drawn out process e.g. "Th eye contact means everything. When the nurses say th "Oh, they want us to sit there for an hour" it's not real truea nurse could really represent something for a patient, that one word, that one eye contact just to give them reassurance that it's okay." – C1
	Optimism: - Nurses feel that they make an effort with service users, but it is not remembered or appreciated	Education	Education: Feedback on behaviour, feedback on outcomes of the behaviour	Feedback on behaviour & outcomes of behaviour: Training film – service users and carers discuss moment they appreciated engagement with a nurse e.g. "I was very against medicationbut one student nurse explain it to meher interaction was very positive, very one-to one, reassuring, so I took the medication orally and wasn't depo-injected which was a positive thing." – SU
MOTIVATION	- Nurses feel that engaging is not always an effective intervention for some service users	Persuasion	Persuasion: Credible source	Credible source : <i>Training film</i> – filmed clips of service users are used as a credible source to help persuade nurses that service users wanted to engage, and that engagement is useful
	Emotion: - Nurses feel anxious about approaching a person who stays in their room and/or somebody they are not sure what to say to	Persuasion	Credible source	As described above
Priority 4: Imp	prove team relations and	ward culture	1	
	Memory, attention, decision:	Enablement	Enablement: Social support (unspecified & practical),	Social support: Check-ins at handover – small changes will be made to nurses' daily routines, for example du

Behavioural analysis using COM-B/TDF (step 4)		Intervention	BCTs	Intervention strategies/mode of delivery (step 8)
		functions (step 5)	(step 7)	
CAPABILITY	- Nurses say they are tired		restructuring the social environment	handover, time will be made to check-in with the nurse team and offer additional support to any team memb that needs it that day
				Restructuring the social environment: Protected Engagement Time – as described in priority 1 & 2
	Social influences: - The ward culture is not open to change	Enablement	Enablement: Social support (unspecified & practical)	Social support: Reflective practice workshops – the w will attend quarterly facilitated workshops that bring clinicians and service users together to discuss, reflec and improve practice
OPPORTUNITY	- The overall ward environment is untherapeutic	Restriction Enablement	Enablement & restriction: Social support (unspecified & practical), restructuring the social	Restructuring the social environment : <i>Protected</i> <i>Engagement Time</i> – as described in priority 1 & 2
			environment	Social support : <i>Compassion Champion</i> – while not path the current <i>Let's Talk</i> toolkit, the co-design team woullike to do ongoing work around implementing a Compassion Champion who advocates for both staff service user wellbeing within the organisation
	Beliefs about capabilities: - Nurses feel helpless - Nurses do not trust everybody on their team to do the job the right way	Enablement	Enablement: Social support (unspecified & practical)	Social support : Check-ins at handover, reflective prac workshops & Compassion Champion – as described a
MOTIVATION	Social /professional identity: - Transient team so no sense of shared responsibility	Enablement	Enablement: Social support (unspecified & practical)	Social support : Check-ins at handover, reflective prac workshops & Compassion Champion – as described at
	Emotion: - Nurses feel frustrated at the lack of managerial support	N/A	N/A	Intervention did not address this directly as it was thought that by implementing measures such as PET, check-ins at handover, reflective practice workshops Compassion Champion, nurses would feel supported
	- Nurses feel burnt out	Enablement	Enablement: Social support (unspecified & practical), restructuring the social environment	Social support: Check-ins at handover – as described above Restructuring the social environment: Protected
				Engagement Time – as described in priority 1 & 2

Discussion

The delivery of high-quality nurse-patient therapeutic engagement is a complex issue that requires input from service users, carers, clinicians and researchers alike. Interventions to improve engagement must be multifaceted and encompass service users', carers' and clinicians' capabilities, opportunities and motivations to engage. We used the methodical and evidence-based framework of the BCW to guide intervention development within a co-design process. This enhanced the process by supporting its "intrinsically desirable qualities" (53) with a robust theoretical underpinning that facilitated a full analysis of existing barriers and behaviours among its principal stakeholders. Although Larkin and colleagues (54) suggest that it may be unrealistic to expect co-design participants to generate solutions to longstanding problems within a short space of time, supporting participants' ideas with a systematic and methodical theory of behaviour change may help mitigate that limitation.

Recent literature encourages a systematic, comprehensive, and transparent approach to intervention development (40). However, many behaviour change interventions are poorly defined and do not use consistent language to describe their mechanisms of action (55,56) making it difficult to pinpoint what did and did not work, which also reduces the ability to compare such interventions (41). The BCW enabled us to identify, understand and describe the mechanisms of action behind *Let's Talk* which is likely to both improve its effectiveness (57) and enable us to review and refine intervention targets after preliminary testing. It also emphasised the importance of addressing nurses' capability, opportunity, and motivation to engage. Previous interventions such as Protected Engagement Time focus predominantly on the opportunities nurses have to engage, but do not consider whether a nurse may be capable or motivated to engage. This may explain why evaluations of PET have not shown improvements in the quality of engagement (58). To our knowledge this is the first intervention aimed at improving engagement to be developed and presented in this comprehensive, systematic, and transparent manner.

Although systematic, the BCW approach may be considered somewhat prescriptive. This can clash with the underlying principles of co-production and co-design, which demand democratic, innovative and creative techniques (59,60). The concept of co-production in mental health was not commonplace even five years ago (61). Traditionally, professional knowledge had a higher status than service users' lived experiential knowledge (62,63). Despite some notable exceptions (e.g., 64,65), service user participation in research was, and often still is tokenistic, with participants having little influence over defining the problems or required changes (63,66). It was essential that

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our process acknowledged, explored and addressed these power differentials so as not to reinforce these entrenched ideals.

Academic language and terminology can preserve power differentials and compromise user and clinician participation (67,68). People who suffer from mental health problems experience effects that can negatively impact cognition and concentration, often exacerbated by medications (69). The use of overly technical language may disproportionally affect people from this group and may lead to exclusion and disempowerment (70), which mirror some of the alienating experiences faced whilst an inpatient on acute wards (e.g., 71). While the COM-B model uses relatively simple terminology (40), the language used to describe the intervention functions was particularly problematic. Intervention functions such as "coercion" and "restriction" may have triggered difficult emotions for some of our participants. These words describe negative ward experiences for example when clinicians coerce service users into taking medication (72), or when liberties are restricted due to treatment under the Mental Health Act 1983 (48). This was also true of the clinicians who participated in our study. Suggesting that they lacked "skills" or "knowledge" was likely to alienate them from the process and make them feel devalued.

To ensure fidelity to the underlying principles of co-design we therefore tailored the BCW approach to the needs of the co-design team. The research team found that providing practical examples of each intervention function, using language from the service users', carers' and clinicians' interviews, was a suitable way of adhering to the principles of co-design and using evidence-based theory in a non-alienating, confirmatory way. Although APEASE criteria were not considered to contain triggering terminology, some of the language was overly technical which also risked alienating co-design team members. The research team therefore translated the APEASE criteria into more accessible language. Furthermore, the co-design team were encouraged to design their own intervention content based on the behavioural analysis. The research team retrospectively assigned BCTs and confirmed these with the co-design team. This adhered to the underlying principles of co-design by foregrounding service user experience (rather than privileging academic knowledge over experiential knowledge), whilst also creating an intervention that could be clearly and methodically described through evidence-based theory and language.

Reflective accounts from three of our co-design team support the steps taken by the research team to ensure an inclusive, participatory process. Whilst the potential for experiential reflections to trigger difficult emotions was anticipated, team members' expressed anxieties were soon 'quashed' by a 'safe and secure' environment in which members 'never felt pressured or judged'. This allowed the service users, carers and clinicians 'to support each other on an equal basis and share a common

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goal'. The opportunity to share personal experiences emerged as an important dynamic across the three reflective accounts. It was variously described as 'a privilege', and an 'incredibly moving' and 'powerful' experience that allowed their expert knowledge to be used 'to implement new models of care and improve quality standards' that 'would make a real difference'. Consequently, these codesign team members described an 'enjoyable' and 'rewarding' process that engendered feelings of pride and empowerment. One member referred to it as a 'life changing' event that promoted selfesteem and self-awareness, and another reported the development of reflective skills. Notable also was the wider outreach and consultation that members undertook through liaison with professional colleagues, services users and carers in various institutional and community arenas, which mirrored their experience of the co-design process. This allowed stakeholders to express any concerns, ask questions and provide feedback. In turn, this led to 'product refinements to make the workbook more accessible and easier to read'. As well as personal impact, these team members described inter-personal benefits including 'feeling (more) engaged with mental health professionals' and managing to 'engage in some really good work' with patients. They were also optimistic about the likely impact of this work moving forward. They sensed that service users and clinicians were *'inspired'* by their work and believed the workbook would have 'a ripple effect...and help create a cultural change within the organisation'. Each of the reflective accounts is provided in full in supplementary file 7.

Beresford (73) argues that frontline clinicians can also be a marginalised group whose voices are often excluded. It is also vital to consider the needs of the service provider whilst embarking on participatory work (74). We implemented several facilitative measures such as providing backfill money so clinicians could attend the feedback and joint workshops and offered flexibility with participation in the small co-design team work e.g., emailing instead of face-to-face meetings and piggybacking staff meetings. However, enabling clinicians to participate equally was challenging. Unfortunately, organisational structures such as shift patterns and staffing levels impacted on clinicians' ability to fully participate. Regular staff meetings or reflective practice groups were also not in place. When given the opportunity to participate, clinicians were motivated, and meaningful participation was possible during the feedback and joint workshops. However, without organisational support structures to provide clinicians time to undertake the ongoing co-design work, much of the prototyping and iterative development of the intervention components were undertaken by the service users. This is a common issue evident in co-design studies in both mental health and general settings (75). There is a need for healthcare organisations to reconfigure their services so clinicians can meaningfully participate in such endeavours and encourage a sense of joint ownership over the work.

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Although the process was highly collaborative and involved service users, carers and clinicians to varying degrees, it was conducted at just one NHS site, which represents a possible limitation. Transferability of our processes to other settings cannot be guaranteed. However, to our knowledge, this is the first time the BCW has been translated for use with participants who have mental health problems and used within an integrated co-design-behaviour change process. This new and novel approach will require further testing to ascertain whether it is suitable and translatable to other intervention development processes. Given that participants were a selfselecting, motivated sample of clinicians, service users and carers, their views may not be representative of all patients and clinicians in the organisation. During the final stage of codesigning Let's Talk the global COVID-19 pandemic took place. We continued our co-design activities remotely, however, a planned quasi-experimental pre-post-test using a structured observational tool (49) had to be postponed. The tool examines the amount, type (e.g. interactive, individual, verbal, non-verbal or solitary) and quality (e.g. positive feedback, praise, smile, ignoring, reprimand, discouragement, neutral behaviours) of nurse-patient interactions (49). Pre-test data on one control and one intervention ward was collected in April – June 2019 and we plan to collect post-test data when we are able to do so and publish the results of this study.

Conclusions

This paper has described the implementation of a new theory-driven co-design/behaviour change approach used to develop the *Let's Talk* intervention toolkit. It offers tools that others may use, or adapt as necessary, to implement the approach in their settings. It also describes the behavioural mechanisms behind the *Let's Talk* intervention toolkit to improve the amount and quality of nursepatient therapeutic engagement on acute mental health wards. Our paper makes a timely and novel contribution to further both participatory methods and behaviour change theory. The approach enhances EBCD by introducing a robust behavioural change theory to help guide the development of a complex intervention. In turn, our participatory approach also enhances the BCW by setting out a practical guide on how to meaningfully involve service users and other stakeholders when designing complex implementation interventions.

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Declarations:

Consent for publication

NC, VD and CS have consented to their reflective accounts being used within this manuscript.

Availability of data and materials

All data generated or analysed during this study are included in this published article and its accompanying supplementary information files.

Competing interests

All authors declare they have no competing interests.

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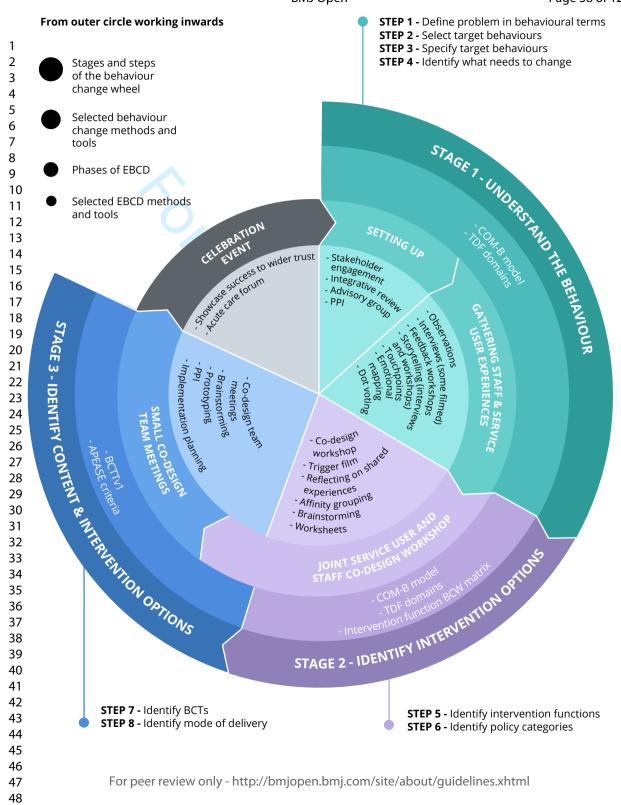
Authors' contributions

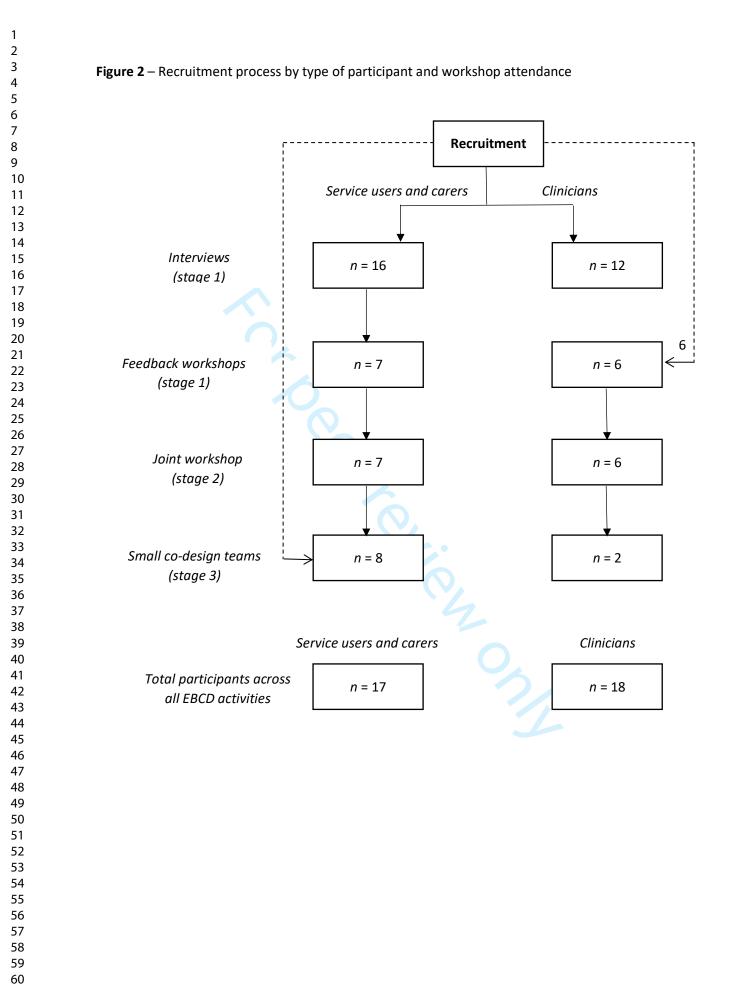
SM conceived of the study, secured the research funding, facilitated the co-design process, analysed the data, contributed to designing intervention components and wrote the manuscript. GR, AS and VT participated in the design and coordination of the study, contributed to the analysis and helped to draft the manuscript. NC, VD and CS participated in the co-design process, contributed to designing intervention components and wrote reflective accounts for the manuscript. All authors read and approved the final manuscript.

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SUPPLEMENTARY 1 – GUIDED Checklist

Item description	Explanation	Page(s) in manuscript where item is located	Other*
1.Report the context for which the intervention was	Understanding the context in which an intervention was developed informs readers about the suitability and transferability of the intervention to the	3-4: Background, 7: setting	
developed.	context in which they are considering evaluating, adapting or using the		
	intervention. Context here can include place, organisational and wider		
	sociopolitical factors that may influence the development and/or delivery of the intervention (15).		
2.Report the purpose of the	Clearly describing the purpose of the intervention specifies what it sets out	3-7: background, 12: define	Systematic integrative
intervention development	to achieve. The purpose may be informed by research priorities, for example	the problem in behavioural	review previously
process.	those identified in systematic reviews, evidence gaps set out in practice	terms	conducted (McAllister et
	guidance such as The National Institute for Health and Care Excellence or		al. 2019)
	specific prioritisation exercises such as those undertaken with patients and		
	practitioners through the James Lind Alliance.		
3. Report the target	The target population is the population that will potentially benefit from the	8: participants	
population for the	intervention – this may include patients, clinicians, and/or members of the	13-14: specify the target	
intervention development	public. If the target population is clearly described then readers will be able	behaviours, Table 2	
process.	to understand the relevance of the intervention to their own research or		
	practice. Health inequalities, gender and ethnicity are features of the target		
	population that may be relevant to intervention development processes.		
4. Report how any published	Many formal intervention development approaches exist and are used to	4-6 and Figure 1	
intervention development	guide the intervention development process (e.g. 6Squid (16) or The Person		
approach contributed to the	Based Approach to Intervention Development (17)). Where a formal		
development process	intervention development approach is used, it is helpful to describe the		
	process that was followed, including any deviations. More general		
	approaches to intervention development also exist and have been		
	categorised as follows (3):- Target Population-centred intervention		
	development; evidence and theory-based intervention development;		
	partnership intervention development; implementation-based intervention		
	development; efficacy based intervention development; step or phased-		
	based intervention development; and intervention-specific intervention development (3). These approaches do not always have specific guidance		
	development (3). These approaches do not always have specific guidance		

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	that describe their use. Nevertheless, it is helpful to give a rich description of how any published approach was operationalised.		
5. Report how evidence from different sources informed the intervention development process.	Intervention development is often based on published evidence and/or primary data that has been collected to inform the intervention development process. It is useful to describe and reference all forms of evidence and data that have informed the development of the intervention because evidence bases can change rapidly, and to explain the manner in which the evidence and/or data was used. Understanding what evidence was and was not available at the time of intervention development can help readers to assess transferability to their current situation.	4, 9-11	Systematic integrative review previously conducted (McAllister e al. 2019) Previously conducted exploratory study (McAlliser & McCrae 2017)
6. Report how/if published theory informed the intervention development process.	Reporting whether and how theory informed the intervention development process aids the reader's understanding of the theoretical rationale that underpins the intervention. Though not mentioned in the e-Delphi or consensus meeting, it became increasingly apparent through the development of our guidance that this theory item could relate to either existing published theory or programme theory.	4-6 and Figure 1	
7. Report any use of components from an existing intervention in the current intervention development process.	Some interventions are developed with components that have been adopted from existing interventions. Clearly identifying components that have been adopted or adapted and acknowledging their original source helps the reader to understand and distinguish between the novel and adopted components of the new intervention.	Table 4 and page 21	
8. Report any guiding principles, people or factors that were prioritised when making decisions during the intervention development process.	Reporting any guiding principles that governed the development of the application helps the reader to understand the authors' reasoning behind the decisions that were made. These could include the examples of particular populations who views are being considered when designing the intervention, the modality that is viewed as being most appropriate, design features considered important for the target population, or the potential for the intervention to be scaled up.	4-6 and Figure 1, 8, and 21 – 25	
9. Report how stakeholders contributed to the intervention development process.	Potential stakeholders can include patient and community representatives, local and national policy makers, health care providers and those paying for or commissioning health care. Each of these groups may influence the intervention development process in different ways. Specifying how differing groups of stakeholders contributed to the intervention development process helps the reader to understand how stakeholders were involved and the degree of influence they had on the overall process. Further detail on how to	8, 11-21	

	integrate stakeholder contributions within intervention reporting are available (19).	
10. Report how the intervention changed in content and format from the start of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	7-16, 12 (Table 4)
11. Report any changes to interventions required or likely to be required for subgroups.	Specifying any changes that the intervention development team perceive are required for the intervention to be delivered or tailored to specific subgroups enables readers to understand the applicability of the intervention to their target population or context. These changes could include changes to personnel delivering the intervention, to the content of the intervention, or to the mode of delivery of the intervention.	This intervention is not designed for subgroups, it is meant for the target population of nurses and service users on acute mental health wards.
12. Report important uncertainties at the end of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	21-25
13. Follow TIDieR guidance when describing the developed intervention.	Interventions have been poorly reported for a number of years. In response to this, internationally recognized guidance has been published to support the high-quality reporting of health care interventions5 and public health interventions14. This guidance should therefore be followed when describing a developed intervention.	11-21, including Table 4
14. Report the intervention development process in an open access format.	Unless reports of intervention development are available people considering using an intervention cannot understand the process that was undertaken and make a judgement about its appropriateness to their context. It also limits cumulative learning about intervention development methodology and observed consequences at later evaluation, translation and implementation stages. Reporting intervention development in an open access (Gold or Green) publishing format increases the accessibility and visibility of intervention development research and makes it more likely to be read and used. Potential platforms for open access publication of intervention	Published in an open access journal.

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development include open access journal publications, freely accessible funder reports or a study webpage that details the intervention development	
process.	

SUPPLEMENTARY 2 – Breakdown of touchpoints to improvement priorities and associated target behaviours

Table 1: Touchpoints from co-design team interviews and ward observations and their overarching themes

Service user touchpoints	Overarching theme
Nurses did not take my concerns into	Do not dismiss me
consideration	
Nurses did not take my physical health seriously	
Nurses blamed my reactions on my mental	
health	
Please respond to my requests in a timely	
manner	
Please explain what you are doing	When you tell me something, please give a
Be clear about your reasons for doing	reason
something	
Introduce yourself to me	
Do not coerce me into doing something	
Listen to me	Please just give me some of your time
I was left on my own	
Lack of engagement results in	
misunderstandings of my problems	
Treat me like a human being	Validate me as a person
Please approach me / help me to approach you	
Forgive and forget	
Understand me and my situation	
Nurses are on the computer all day	Unhelpful behaviours
I need privacy for one to ones	7
Nurses give me robotic, one-size-fits all care	
Staff touchpoints	Overarching themes
We want better team relations	Improving ward culture
Needs to be more openness to change within	
the team	
Improvement in staff-managerial relations	
Improve the culture around response	
Bring the fun back into the job	
Create better bonds with service users	Improving interactions with service users
Streamline working practices to create / free up	
time for interactions	
Improve the way things are communicated to	
service users	
Improve the way messages are handed over	
within the team	

Table 2 – Service user improvement priorities and target behaviours drawn from touchpoints by discussion with co-design team, emotional mapping exercise and dot voting

Overarching improvement priorities	Target behaviours
Nurse-patient communication needs to be	Help me to approach you / give me different
improved	ways to communicate with you
	Do not dismiss me or make me feel like a
	burden / take my concerns seriously
	We need calm, rational conversations with
	nurses
Treat me like a human being	Do not give me robotic care / one size fits all
	care
	Do not coerce me into doing something
Forgive and forget	Please be motivated to know who I am as a
	person, not just a diagnosis
	Remember that you do not see me at my best
Help me help myself	Create a safe space for me to interact with you
	Nurse to support me / give me practical advice
	Nurse to explain why I am on the ward early on
	in admission
	Nurse to be specific about what will happen to
	me regarding my medication, admission, and
	discharge
	Nurse to help me to understand myself

Table 3 – staff improvement priorities and target behaviours drawn from touchpoints by discussion with co-design team, emotional mapping exercise and dot voting

Overarching improvement priorities	Target behaviours
Improve the way we communicate with service	Keep in check my tone of voice
users	Ensure I fully explain what I am doing to service
	users
	Do not promise things I cannot give
	Ensure there is a consistent message being
	delivered by the team
Improve the way that leave is communicated	Ensure all staff are aware when service users'
	leave changes
	Explain leave rights to service users
Improve the culture around response	When I hear the alarm, I will respond in a
	timely manner
	I will step in to help my colleagues if they need
	it
	I will ensure service users do not have to step in
	to help defuse a situation that does not involve
	them
Improve the way messages are handed over	Be clear and concise when handing messages
within the team	over to the team
	Ensure I handover messages to the nurse in
	charge

When a servic	e user tells me something, I will
ensure I recor	d it in the notes or tell the nurse
in charge	

Table 4 – joint improvement priorities and target behaviours

Joint priorities	Service user and staff priorities they came from
Communicating with withdrawn people	Nurse-patient communication needs to be
	improved (staff)
	Improve the way things are communicated to
	service users (service user)
	Treat me like a human being (service users)
Improving team relations and improving overall	Communicating leave (staff)
communication with service users	Improve the culture around response (staff)
	Improve the way messages are handed over within
	the team (staff)
Nursing staff to help service users help	Help me help myself (service users)
themselves	Treat me like a human being (service users)
	Improve the way things are communicated to
	service users (service users)
	Nurse-patient communication needs to be
	improved (staff)
	Forgive and forget (service users)
Improve nurses' confidence when interacting	Improve the way things are communicated to
with service users	service users (staff)

Write improve	ment priority here
Things that cur	rrently get in the way of this being done in practice (use your COM-B barriers to he
stimulate ideas	
Why this shoul	ld be improved (think about what needs to be done differently in practice to make
improvement h	
	4
	tion (think about when / where / with whom should this be done with. Use the
	tion (think about when / where / with whom should this be done with. Use the ples provided to help stimulate ideas)
practical exam	ples provided to help stimulate ideas)
practical exam	

SUPPLEMENTARY 4 – APEASE criteria translated for use with co-design team

Table 1: APEASE criteria and lay translation

APEASE from BCW book by Michie et a	I. Lay translation used with co-design team
Affordability	Can the organisation afford what we are proposing?
	What are the long-term costs of the intervention?
	• Can these be covered in the future?
Practicability	Who are the key people who would drive the intervention forward?
	Could this become a normal part of ward care / ward work?
	Would people know how to use the intervention?
	 If not, what can we put in place to help them with this?
	Are there enough resources for nurses to be able to use the intervention?
	 If not, what could be put in place to help with
	this?
	Will nurses be able to modify the way they work with the intervention?
Effectiveness and cost effectiveness	How many service users, carers or clinicians could the
	intervention help?
Acceptability	Will nurses want to do this?
	Will service users want to do this?
	Do I think this intervention will help service users, carers and clinicians?
	Do you think the effects of the intervention will have a positive impact on nurses' work / patient care?
Side effects / safety	Can we think of any unintended consequences if we
	implement the intervention? • What can we do to minimise these?
Equity	Will this intervention be fair to everyone?
. ,	 If not, what can be put in place to make it fairer?

Would you like to talk?

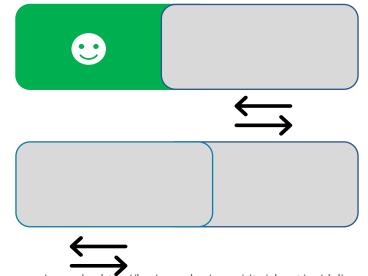


Sometimes we don't want to talk because we feel too distressed or we don't have the right words to say.

That is okay. Many people feel this way.

But it's important to catch the moment if you feel like talking.

If that feeling comes, slide the card on the front of your door to green and a nurse will arrange some time to have a chat with you.





A workbook to help you structure your conversations with your nurse



PART 1

My stress cup

Managing my medication & side effects

PART 2

Weekly planner

What are ward rounds?

Preparing for my ward round



Reflection mirror

Understanding how I feel

PART 4

My discharge needs My next steps Contacts & support Useful contacts



This workbook came about because a very dedicated group of service users, nurses and clinicians wanted to improve the interactions that nurses and service users have on acute mental health wards.

The following pages have been fully co-designed by a group of service users, nurses and clinicians from [removed for confidentiality] NHS Foundation Trust, and a researcher and mental health nurse from King's College London.

To everybody who has had input into the making of this book, we are thankful.



How to use this workbook

Use this workbook with your nurse to:

1) Help you understand your experiences

2) Organise your ward rounds

3) Plan your discharge

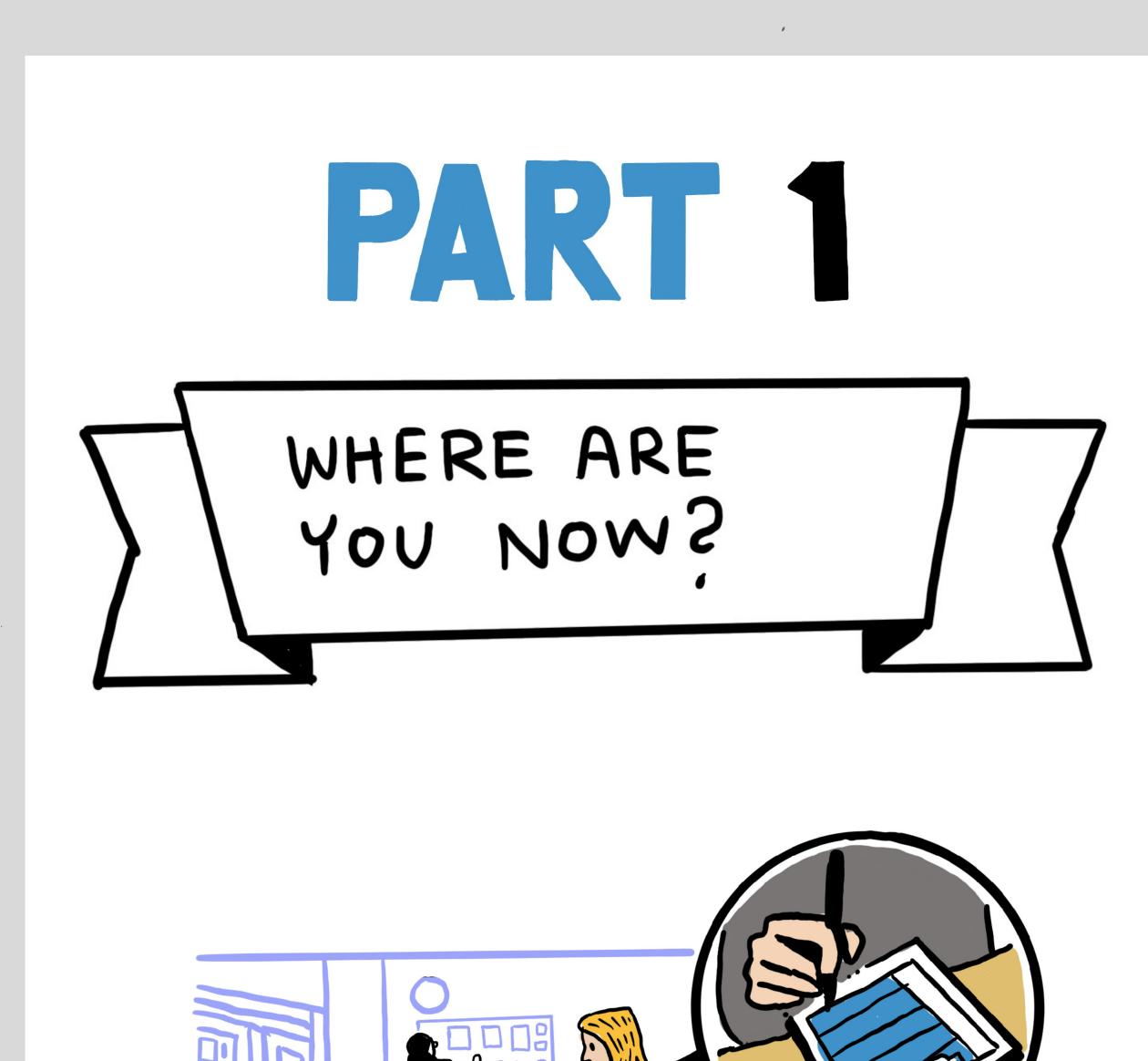
Work through the book at your own pace.

There's no need to do all the exercises at once.

Do as many or as few of the exercises as you like.

You can ask your nurse to help or do some of the exercises on your own.







Complete these exercises early on in your admission



Show how full your cup is with stress.

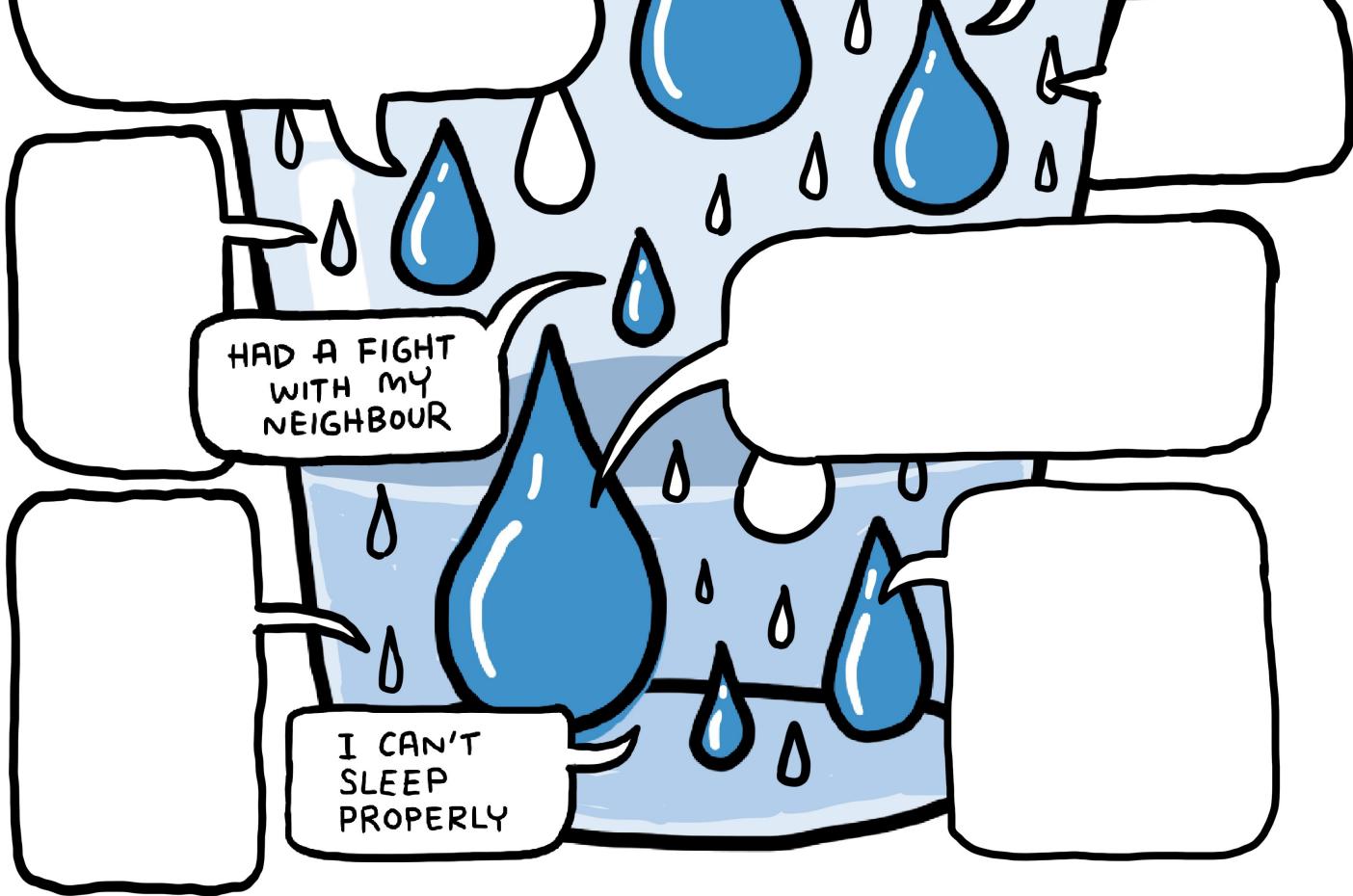
Write your small stressors in the speech bubbles from the small water droplets and your big stressors in the speech bubbles from the big water droplets.

This exercise should be done with your nurse so they can help you to manage your stressors.



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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 22	MY STRESS CUP	
22 23 24 25 26 27 28 29 30 31 32 32 31 32 32 31 32 32 31 32 32 31 32 32 31 32 32 31 32 32 31 32 32 31 32 32 32 32 32 32 32 32 32 32 32 32 32		
47 48 49 50 51 52 53 54 55 56 57 58 59 60		





Write the medications your doctor prescribes during your admission:

Medication:	Dose:
Medication:	Dose:

Use this table with your nurse to better understand the good and bad parts of taking or not taking your medication.

You can use the outcome of this in your ward rounds to tell the

(

doctor and nurses how you feel

What I like about not taking my medication	What I don't like about taking my medication
What I don't like about not taking my medication	What I like about taking my medication
15-minute exercise	
exercise	

33 34

46 47 48

49 50 51

57

59



Sometimes your medications will give you side effects.

When you are put on a new medication, use this chart to mark how it makes you feel.

Compare how different medications make you feel.

Work through this with your nurse and use it in ward round so your care team can understand how you are feeling and help you find the medication that is right for you.

= no side effects, 5 = worst side effects.

	I	2	3	4	5
MEDICATION:					
DOSE:					
MEDICATION:					
DOSE:					
MEDICATION:					
DOSE:					
MEDICATION:					
DOSE:					
MEDICATION:					
DOSE:					





Helping you organise ward rounds, plan your days and chart your progress



Ways to use this planner:

- 1) Schedule 1:1 time with your nurse
- 2) Record time and day of group activities
- 3) Make note of important appointments
- 4) Plan activities to do when you get SI7 leave

** If you need more than one week, ask your nurse to print you out more pages **



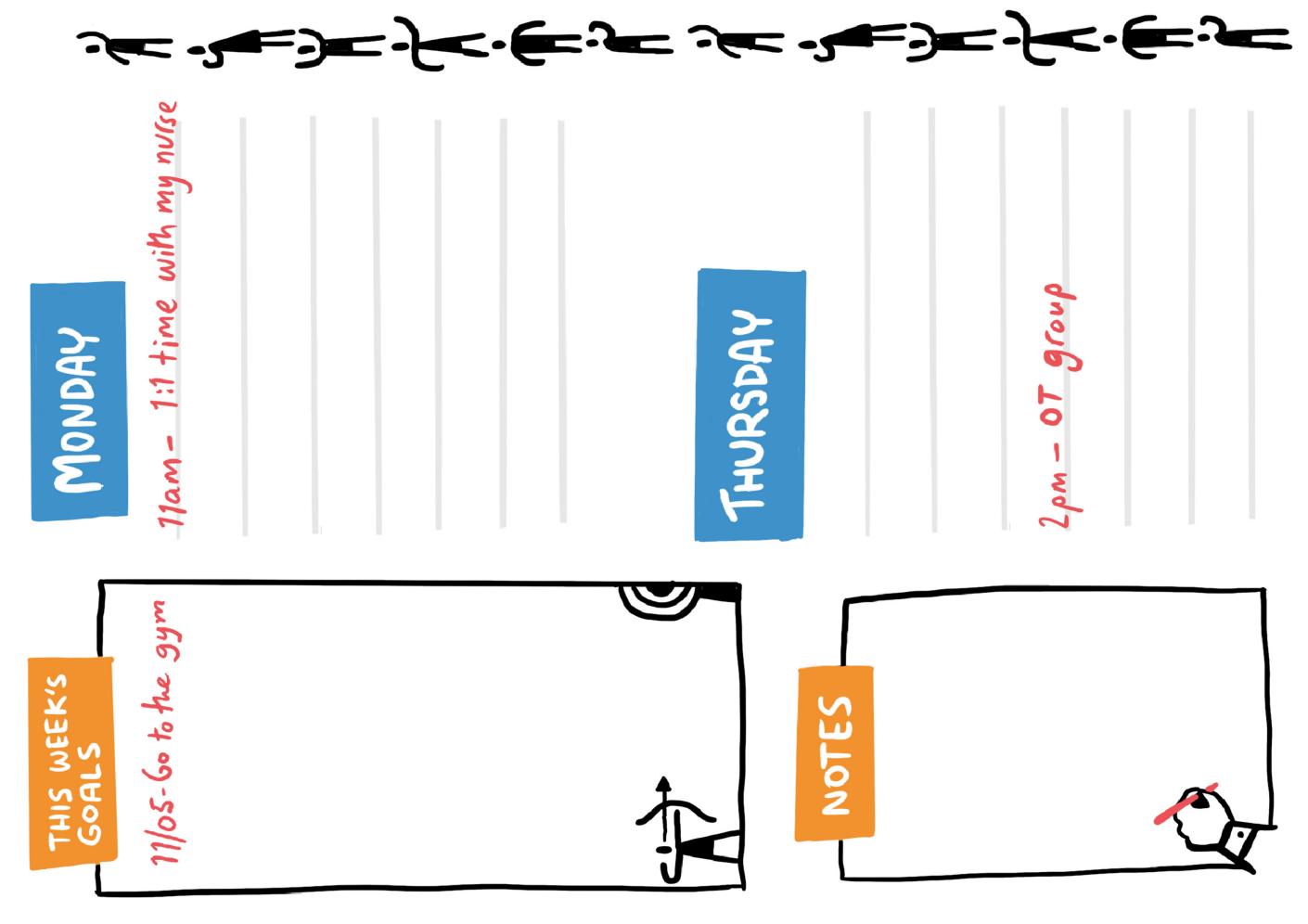






FRIDAY







Ward rounds will play an important and beneficial role in your care.

They will happen once a week.

The goals of ward round are to:

Have calm conversation with staff about your care

59

Find the best medication for you

Discuss your progress

Have your voice heard

You'll be given a "preparing for my ward round" worksheet at the end of each ward round.

This will help you to plan what to say at your next ward round.

Ask your nurse to help you fill this in if you need help.



There may be several professionals sitting around the table.

Some professionals who might be at the table will include your consultant psychiatrist, a nurse, people from your community care, the OT, or pharmacist.

You can bring a relative, carer or advocate to your ward round.



If you feel overwhelmed by the amount of people at your ward round, you can request that fewer people attend.



If you have any questions or you want some help to prepare for your ward round, Speak to your nurse and ask for a 1:1.







It is important you go to your ward round so you can talk about your care and raise any concerns you may have

Bring this to your next ward round so you can remember the things you want to talk about

Write down any questions you may want to ask in ward round

Some questions might include:

- What can 1 do to improve my mental wellbeing
- Are there any medications that may help?
- What help is available for a specific problem or issue you're having?



Things the doctor may ask you in ward round:

How are you feeling today?

How is your medication?

How are you coping on the ward?

What are your goals for ward round?

22 23

29

35

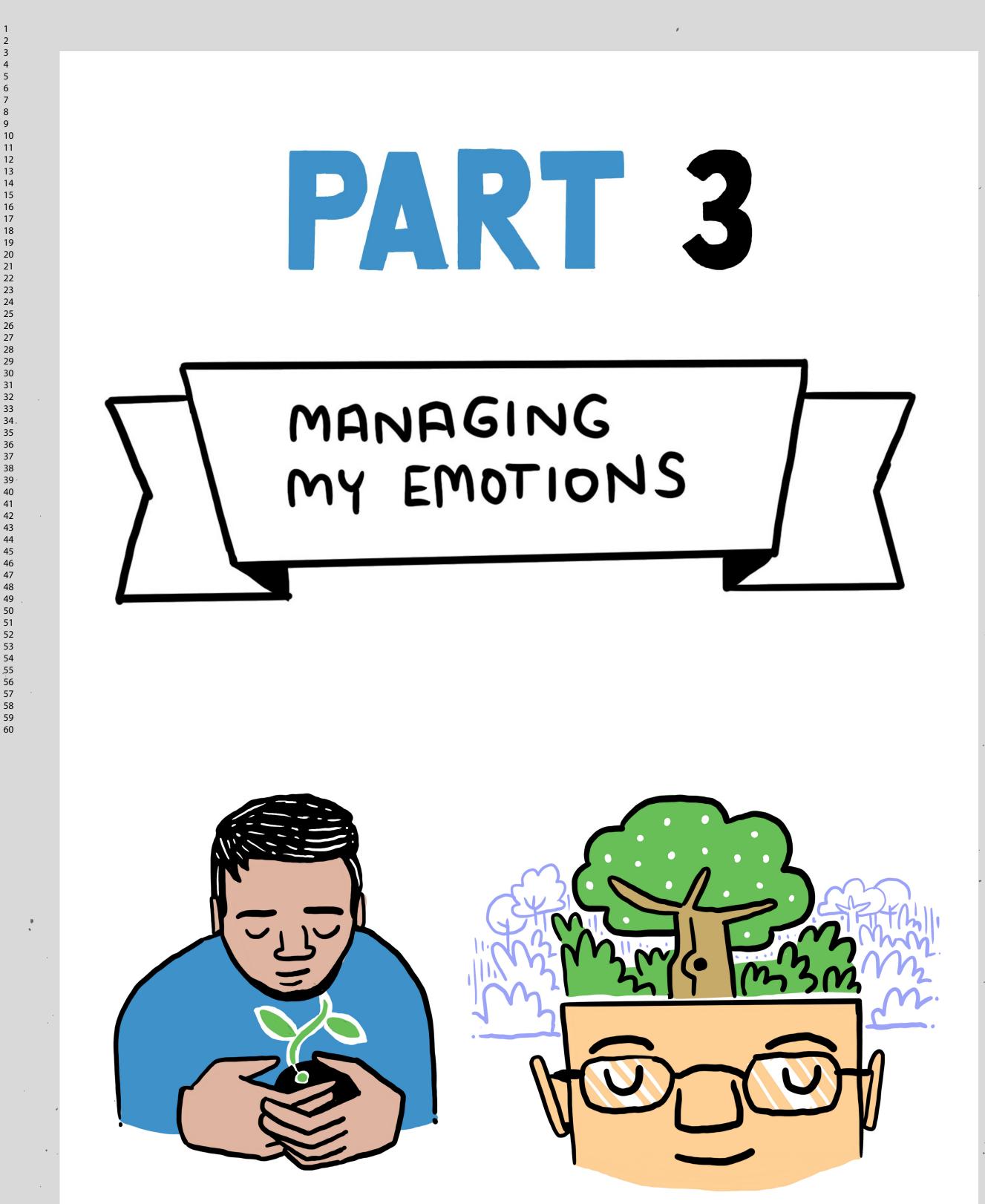


The box below lists areas of your life you may wish to talk about at ward round.

Try to fill this out on the day of your ward round.

I = awful, 5 = excellent

	I	2	3	4	5
Mood					
Anxiety					
Thoughts					
Sleep					
Appetite					
Exercise					
Relationships					
Social life					
Work / study					
Drugs / alcohol					
Medication					
Physical health					



Some time for reflection and understanding how you feel



"Mirror" by Cady Stone (service user expert by experience)

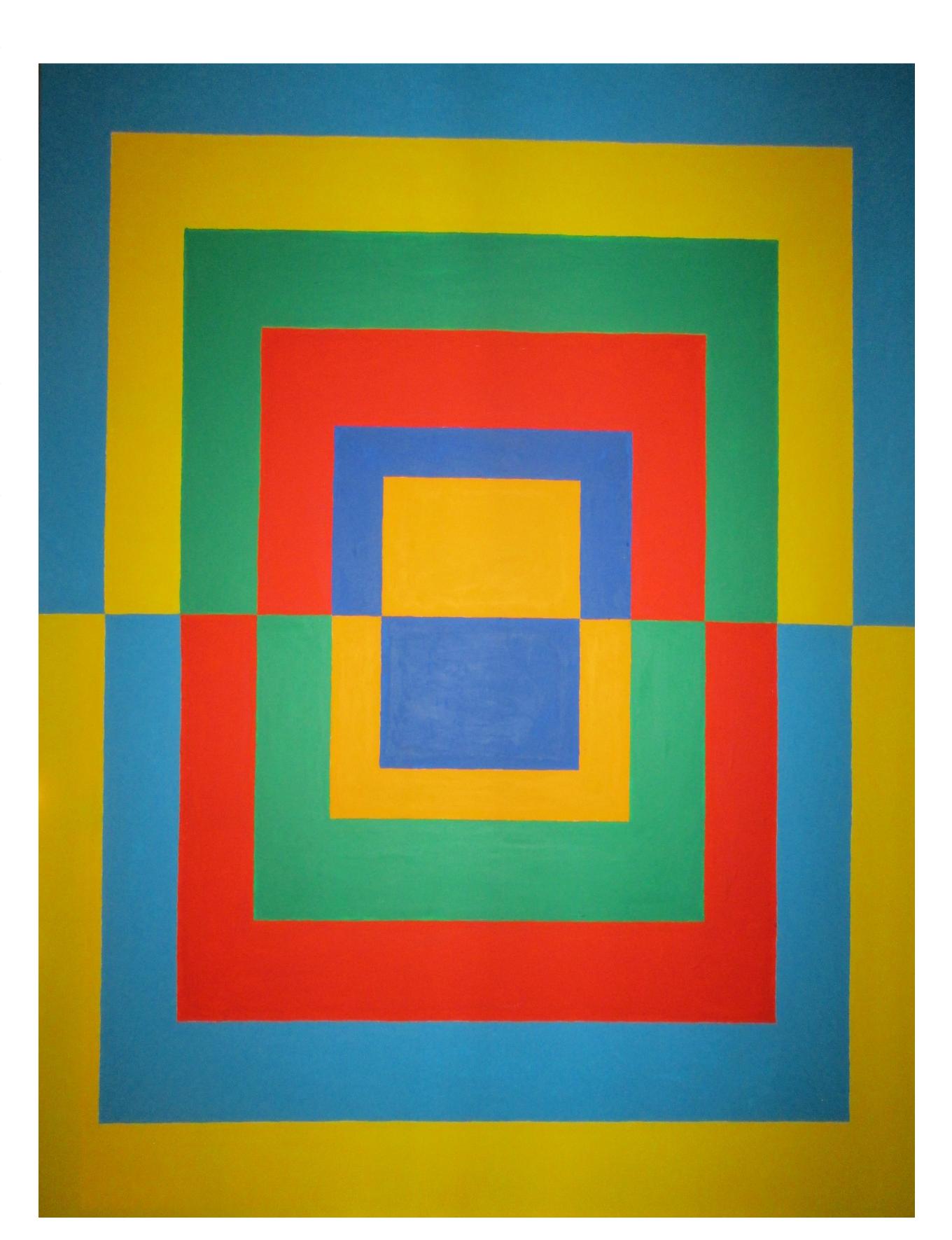
Mirror suggests the idea of walking through an empty corridor, like the ones I experienced in an acute ward.

It represents that terrifying moment of being "locked in" and not being able to leave to get fresh air outside.

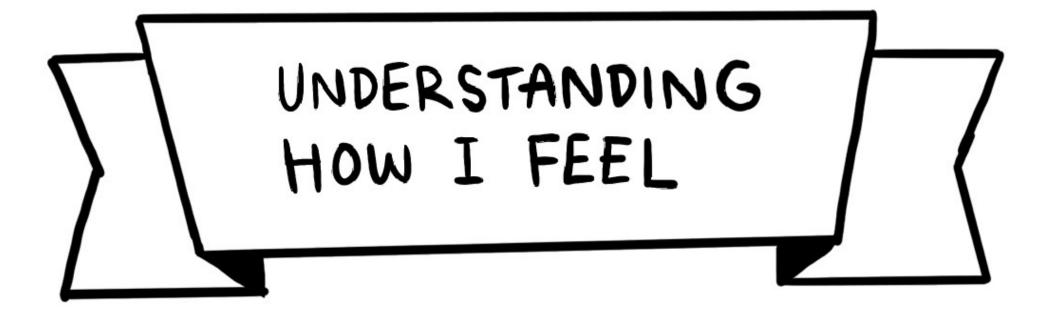
The colours reflect the wonderful daylight once I was able to go out on escorted leave.

The title, "Mirror", refers to the self reflection that can lead to recovery.

http://bmjopen.bmj.com/site/about/guideline







Some people may find it difficult to give a word to the emotions they are feeling.

Use the emotions table on the next page to find the words to explain how you feel.

You can use this on your own or as an activity to do with your nurse.



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ED. SHATTERED E · CHEERLESS DEVA STATED OKEN · GUTTED ED · GLOOMY

ETTED · MUMBLED GRUMBLED **ITERED**



ED. DISTRAUGHT UICKY. WORRIED D. ALARMED IN A STATE · ANXIOUS

· GULPED · WAILED STAMMERED SPERED

CALM . PEACEFUL . COSY STRESS-FREE . COOL SELAXEU SU

COMPOSED . UNRUFFLED BLISSFUL · SERENE UNPERTURBED UTTERED · STATED · AGREED CHATTED . GOSSIPED DISCUSSED

LONELY

LONE SOLITARY ABANDONED · DESERTED LOST . FORLORN . ALONE FRIENDLESS · ISOLATED

CUT-OFF

SIGHED · MOANED · BAWLED

MUTTERED.GRUMBLED

SNIFFLED

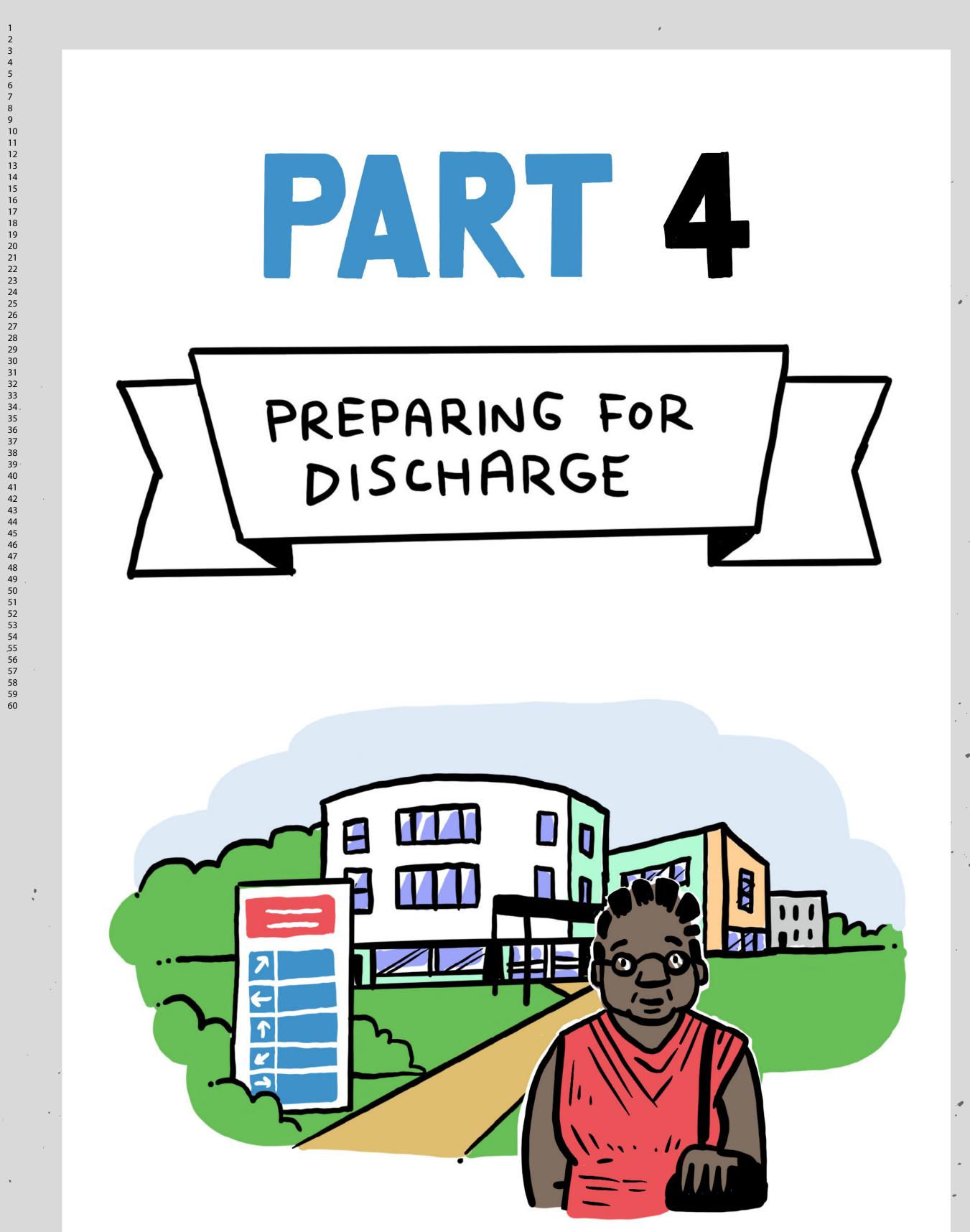
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DEPRESSE miserabl miserabl heartbro demoralis crushed.	SOBBED - WEPT - FRE SPLU1	FRIGHTEN	TERRIFIE STARTLED UPSET-PAN DISTRESS TROUBLED	STUTTERED GASPED -
CONTENT • GLAD • JOYFUL CHEERFUL • IN HIGH SPIRITS JOVIAL • OVERJOYED THRILED • DELIGHTED • PLEASED ON CLOUD NINE	GUSHED • EXCLAIMED CHEERED • JokeD • BRAGGED GIGGLED	Reg Sec Sec Sec Sec Sec Sec Sec Sec Sec Sec	ANNOVED - IRRITATED FUMING - LIVID - CROSS FUMING - LIVID - CROSS FRUSTRATED - ENRAGED INFURIATED - INCENSED UP IN ARMS	SNAPPED · YELLED · BOOMED SHRIEKED · BELLOWED GROWLED









Building support for once you're home

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MY DISCHARGE NEEDS

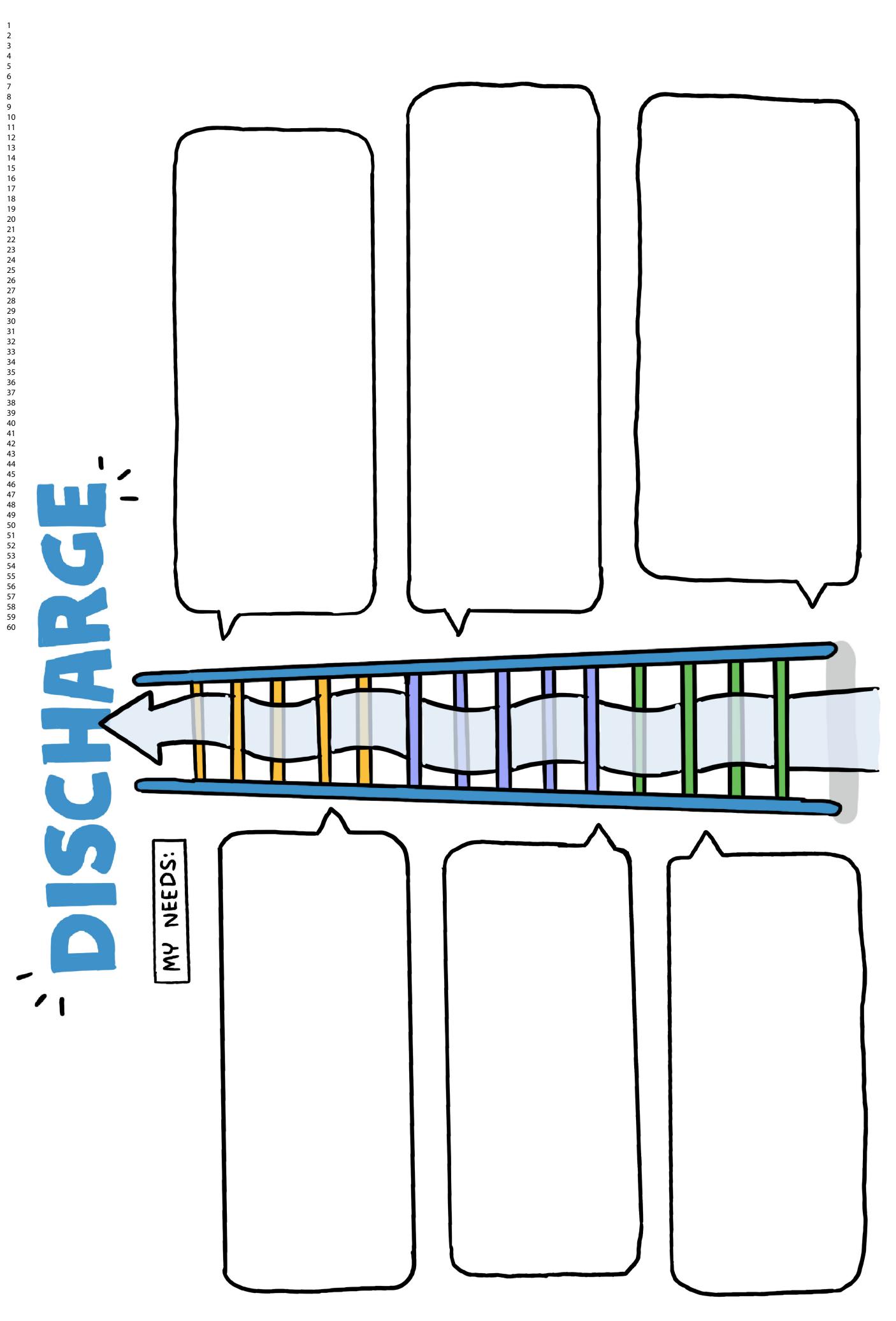
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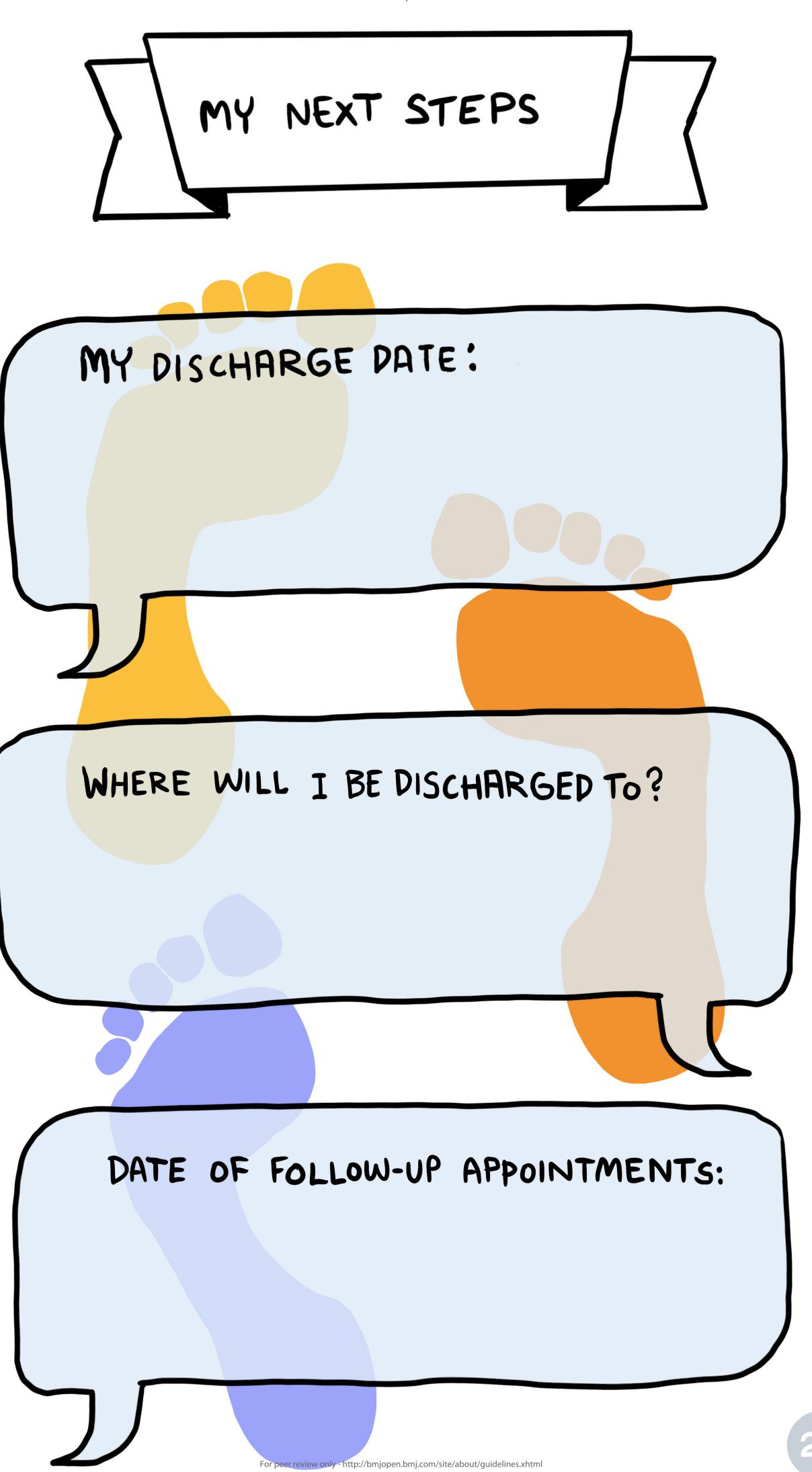
Use this ladder to write down things you'll need in place for when you leave hospital.

Show it to your nurse so they can help you put these things in place.



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WHO WILL SUPPORT ME AFTER DISCHARGE?

MY CARE CO-ORDINATOR IS:

MY CARE CO-ORDINATOR'S CONTACT DETAILS:





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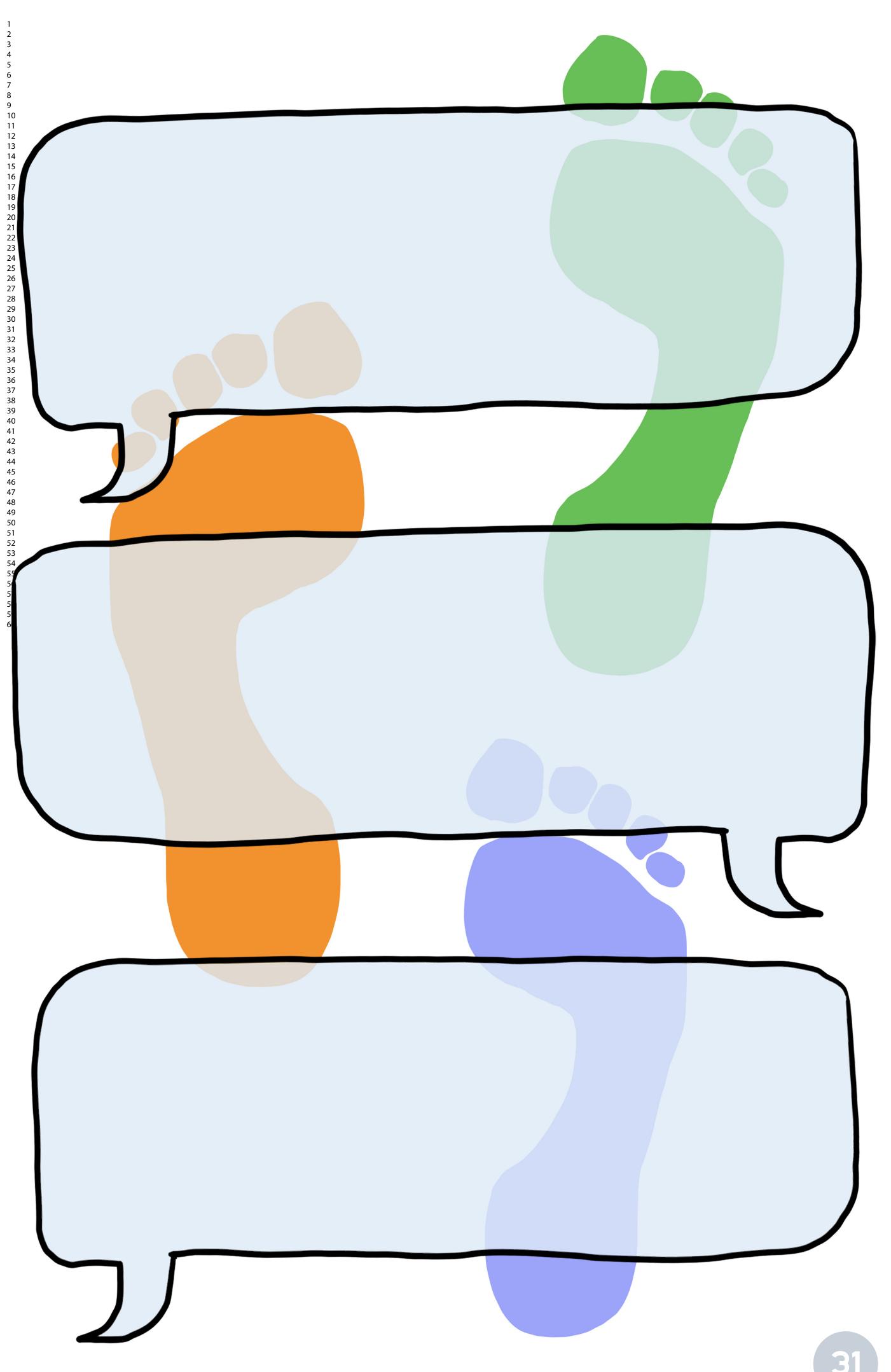
MY DISCHARGE MEDICATION IS:

QUESTIONS FOR MY INPATIENT CARE TEAM:

QUESTIONS FOR MY CARE CO-ORDINATOR:

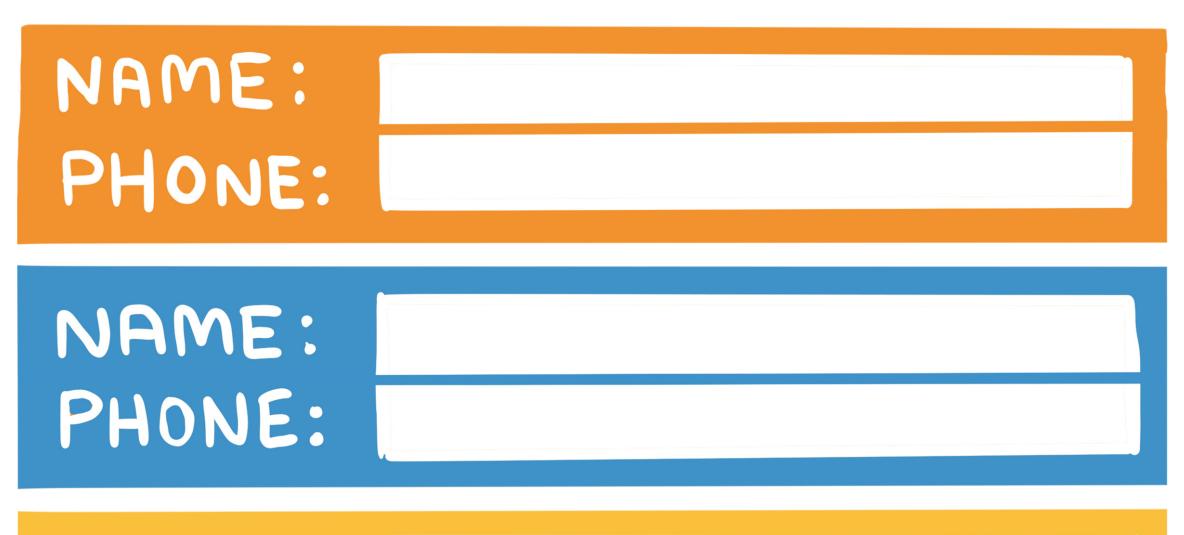








Use these pages to make note of the people you will call if you're not feeling at your best.



PHONE:

NAME: PHONE:

NAME: PHONE:

NAME: Phone:

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 $\begin{array}{c}1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\2\\13\\14\\15\\16\\17\\8\\9\\0\\1\\2\\2\\3\\2\\4\\2\\5\\2\\6\\7\\8\\9\\0\\1\\2\\3\\3\\4\\5\\6\\7\\8\\9\\0\\1\\4\\2\\3\\4\\4\\5\\6\\7\\8\\9\\0\\1\\5\\5\\5\\6\\7\\8\\9\\0\end{array}$

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SUPPLEMENTARY 7 – Reflective accounts of the co-design process from members of the co-design team

Box 1 – Reflections from the co-design team

The study of therapeutic engagement in acute hospital wards is something that makes me feel proud and engaged with mental health professionals. During the course of the study staff members and service users attended regular meetings and workshops to discuss the development of the interventions. We all shared our experiences and identified what needed to be improved within hospital wards and came up with ideas about how we could do this. The project led to presentations at service user group at the Trust headquarters and eventually at an acute care forum at the Indian YMCA.

I co-designed the workbook. At the beginning, the first edit was too heavy to grasp. There was too much information for acute patients with their nurse to understand. When we took it to the service user group the feedback we got was not very positive and so we had to refine it. We made the workbook more accessible, easier to read with colourful diagrams.

The filmed interviews of service users reviewed the experiences of nurse-patient interactions in hospital wards. With the data collected we co-designed a thirty-minute film that was recorded and edited along with the workbook. The film was watched by staff and service users at an acute care forum and people were given the opportunity to express their concerns and ask questions. At the acute care forum everyone was given a copy of the workbook and encouraged to consult the co-design team. People reported a better understanding of patient experiences with nurses and were inspired by what we had to say.

For myself as having my mum as a carer, being involved in such a co-design project was very rewarding and felt like giving something back to those people who supported me to recovery and wellbeing. The relationship between patient and nurses needs to be addressed. I had a poor connection and interaction of staff on wards who were not properly trained to do their job. The workbook is a valuable tool that highlights the important information that matters to the patient. As a service user, the project was an opportunity to tell my story of the experiences of being detained, not really acknowledging what was going on around me, especially with staff working along with the experts delivering inpatient care.

Cady Stone (service user co-design team member working on priority 2 & 3)

Box 2 – Reflections from the co-design team

It was early 2018 when I was invited to join a workshop for a study using an experience based co-design (EBCD) methodology to bring staff and service users together to co-design solutions to improve nurse-patient therapeutic engagement on acute mental health wards. The first time I heard about EBCD was in 2015, and I immediately agreed to be part of it.

Through the EBCD journey I've had the privilege to revisit my life story through my personal narrative. It was life changing, it served as a redistribution of ownership and power to my personal life history. Using my own life experiences as a tool to implement new models of care and improve quality standards. Furthermore, it helped my self-esteem and increased my self-awareness. Service users and carers play an increasingly important role in a variety of activities especially in research. What is crucial in their involvement is to build a relationship where professionals and users/carers can support each other on an equal basis and share a common goal. Trust, respect and value are crucial.

What I personally experienced with this research was an amazing collaboration between the researcher, patients and healthcare professionals. Everyone felt always at ease to speak and give their views and experiences on a level of mutual collaboration. No barriers to patients' ideas but collective decision-making. Each person generously shared their incredibly moving testimony of struggle, survival and strength with great dignity and drive to use their adverse experience to make a real difference.

The co-designed activities and events did not only serve the research as a whole but they inspired the creation of a workbook to encourage a model of therapeutic engagement, signs to help nurses and patients identify when they need to talk further interventions that can ease and improve an inpatient's journey. An incredible toolkit that will have a ripple effect making a difference and help create a cultural change within the Trust.

Vittoria De Meo (carer co-design team member working on priority 2, 3 & 4)

Box 3 – Reflections from the co-design team

For anyone who is hospitalised due to their mental health, processing when, where or what is happening can be a very challenging experience. Feelings of hopelessness, confusion, isolation and worry all cloud your thinking, whilst the mantle of looking after yourself is taken away and placed in the arms of complete strangers. For me, as a service user, taking part in a study which aims to improve the interaction between those who care (nurses) and those receiving care (service users) was an easy one. Having the opportunity to make real change was and still is exciting.

Going into the study, I was not sure what to expect. This was the first time that I had done anything like this, so it was new ground for me. A simple recollection can cause difficult emotions to surface again and, in some cases, result in serious distress. However, my anxieties were soon quashed, and I was offered a safe and secure space to share my experiences. Throughout the conversations I never felt pressured or judged, I actually felt empowered. Empowered that my experiences were being taken seriously and will contribute to a wider narrative.

Over the following months I was invited to attend collaborative meetings with the other services users and staff involved with the project. Listening to everyone's accounts and testimonies was quite powerful. Reflecting on the good, the bad and what could be achieved. All of this was neatly woven into a film which was both informative and emotive.

Finally, after agreeing on our recommendations I began working on nurse-patient communication. We made our work even more specific, targeting people who isolate themselves in their rooms. What was insightful was working and hearing from other

professionals, utilising their experiences to develop an idea that was both practical and simple. Our main idea was a slider that would be mounted on a service user's door and would allow them to choose between a smiley or a sad face (depending on their mood). Thus, indicating to nursing staff if the service users would like to engage or not.

I really enjoyed contributing my thoughts to this idea as the idea of engaging with service users who withdraw really resonates with me. In my 'day job' I am a Peer Support Worker at an acute hospital, and this is quite common. I discussed with my colleagues what they thought of the idea, I am pleased to say it was warmly received. I also identified a service user on the ward who matched the type of individual we were trying to help. Taking part in the study therefore directly affected how I approached service users and subsequently, I have managed to engage in some really good work with the individual.

Throughout the process of this study, I have always felt empowered to share my views and experiences. Whether this was in our group work or whilst recording my testimony. I have also learnt the power of networking to build and develop ideas alongside the ability to reflect. Reflection in my opinion has been a key thread which I have experienced throughout taking part in this study. Not just the reflection on what I had experienced as an inpatient, but also it allowed me the time and space to reflect on what really mattered to those going through similar experiences now.

Nick Canham (Peer Support Worker & service user co-design team member working on priority 1)

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SUPPLEMENTARY 1 – GUIDED Checklist

Item description	Explanation	Page(s) in manuscript where item is located	Other*
1.Report the context for which the intervention was developed.	Understanding the context in which an intervention was developed informs readers about the suitability and transferability of the intervention to the context in which they are considering evaluating, adapting or using the intervention. Context here can include place, organisational and wider sociopolitical factors that may influence the development and/or delivery of	3-4: Background, 7: setting	
2.Report the purpose of the intervention development process.	the intervention (15). Clearly describing the purpose of the intervention specifies what it sets out to achieve. The purpose may be informed by research priorities, for example those identified in systematic reviews, evidence gaps set out in practice guidance such as The National Institute for Health and Care Excellence or specific prioritisation exercises such as those undertaken with patients and practitioners through the James Lind Alliance.	3-7: background, 12: define the problem in behavioural terms	Systematic integrative review previously conducted (McAllister et al. 2019)
3. Report the target population for the intervention development process.	The target population is the population that will potentially benefit from the intervention – this may include patients, clinicians, and/or members of the public. If the target population is clearly described then readers will be able to understand the relevance of the intervention to their own research or practice. Health inequalities, gender and ethnicity are features of the target population that may be relevant to intervention development processes.	8: participants 13-14: specify the target behaviours, Table 2	
4. Report how any published intervention development approach contributed to the development process	Many formal intervention development approaches exist and are used to guide the intervention development process (e.g. 6Squid (16) or The Person Based Approach to Intervention Development (17)). Where a formal intervention development approach is used, it is helpful to describe the process that was followed, including any deviations. More general approaches to intervention development also exist and have been categorised as follows (3):- Target Population-centred intervention development; evidence and theory-based intervention development; partnership intervention development; implementation-based intervention development; efficacy based intervention development; step or phased- based intervention development; and intervention-specific intervention development (3). These approaches do not always have specific guidance	4-6 and Figure 1	

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	that describe their use. Nevertheless, it is helpful to give a rich description of how any published approach was operationalised.		
5. Report how evidence from different sources informed the intervention development process.	Intervention development is often based on published evidence and/or primary data that has been collected to inform the intervention development process. It is useful to describe and reference all forms of evidence and data that have informed the development of the intervention because evidence bases can change rapidly, and to explain the manner in which the evidence and/or data was used. Understanding what evidence was and was not available at the time of intervention development can help readers to assess transferability to their current situation.	4, 9-11	Systematic integrative review previously conducted (McAllister e al. 2019) Previously conducted exploratory study (McAlliser & McCrae 2017)
6. Report how/if published theory informed the intervention development process.	Reporting whether and how theory informed the intervention development process aids the reader's understanding of the theoretical rationale that underpins the intervention. Though not mentioned in the e-Delphi or consensus meeting, it became increasingly apparent through the development of our guidance that this theory item could relate to either existing published theory or programme theory.	4-6 and Figure 1	
7. Report any use of components from an existing intervention in the current intervention development process.	Some interventions are developed with components that have been adopted from existing interventions. Clearly identifying components that have been adopted or adapted and acknowledging their original source helps the reader to understand and distinguish between the novel and adopted components of the new intervention.	Table 4 and page 21	
8. Report any guiding principles, people or factors that were prioritised when making decisions during the intervention development process.	Reporting any guiding principles that governed the development of the application helps the reader to understand the authors' reasoning behind the decisions that were made. These could include the examples of particular populations who views are being considered when designing the intervention, the modality that is viewed as being most appropriate, design features considered important for the target population, or the potential for the intervention to be scaled up.	4-6 and Figure 1, 8, and 21 – 25	
9. Report how stakeholders contributed to the intervention development process.	Potential stakeholders can include patient and community representatives, local and national policy makers, health care providers and those paying for or commissioning health care. Each of these groups may influence the intervention development process in different ways. Specifying how differing groups of stakeholders contributed to the intervention development process helps the reader to understand how stakeholders were involved and the degree of influence they had on the overall process. Further detail on how to	8, 11-21	

	integrate stakeholder contributions within intervention reporting are available (19).	
10. Report how the intervention changed in content and format from the start of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	7-16, 12 (Table 4)
11. Report any changes to interventions required or likely to be required for subgroups.	Specifying any changes that the intervention development team perceive are required for the intervention to be delivered or tailored to specific subgroups enables readers to understand the applicability of the intervention to their target population or context. These changes could include changes to personnel delivering the intervention, to the content of the intervention, or to the mode of delivery of the intervention.	This intervention is not designed for subgroups, it is meant for the target population of nurses and service users on acute mental health wards.
12. Report important uncertainties at the end of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	21-25
13. Follow TIDieR guidance when describing the developed intervention.	Interventions have been poorly reported for a number of years. In response to this, internationally recognized guidance has been published to support the high-quality reporting of health care interventions5 and public health interventions14. This guidance should therefore be followed when describing a developed intervention.	11-21, including Table 4
14. Report the intervention development process in an open access format.	Unless reports of intervention development are available people considering using an intervention cannot understand the process that was undertaken and make a judgement about its appropriateness to their context. It also limits cumulative learning about intervention development methodology and observed consequences at later evaluation, translation and implementation stages. Reporting intervention development in an open access (Gold or Green) publishing format increases the accessibility and visibility of intervention development research and makes it more likely to be read and used. Potential platforms for open access publication of intervention	Published in an open access journal.

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development include open access journal publications, freely accessible funder reports or a study webpage that details the intervention development	
process.	

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Title: Developing a theory-informed complex intervention to improve nurse-patient therapeutic engagement employing Experience-based Co-design and the Behaviour Change Wheel: an acute mental health ward case study.

Authors: Sarah McAllister^{*}, Professor Alan Simpson, Dr. Vicki Tsianakas, Nick Canham, Vittoria De Meo, Cady Stone, Professor Glenn Robert

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Keywords: Behaviour Change Wheel; Complex Intervention; Experience-based Co-design; mental health nursing; nurse-patient therapeutic engagement

Word count: 5,371 – We have noticed that word counts in papers previously published by BMJ Open vary considerably, with some having up to 8,000 words. We recognise our paper is over the recommended 4,000 words, however we believe this is justified for the following reasons. First, this is a qualitative piece of work that aims to present both a new method for intervention development and systematically report a new intervention. To ensure the process is clear enough for others to replicate and also understand the mechanisms behind how the intervention works, it requires more than 4,000 words. Second, we currently have another paper under review, which reports in more detail the early stages of our process. To avoid salami slicing our work, we feel it is important that this part of our process is reported as one complete paper.

Title: Developing a theory-informed complex intervention to improve nurse-patient therapeutic engagement employing Experience-based Co-design and the Behaviour Change Wheel: an acute mental health ward case study.

ABSTRACT

Objectives: Our objectives were threefold: 1) describe a collaborative, theoretically driven approach to co-designing complex interventions; 2) demonstrate the implementation of this approach to share learning with others and 3) develop a toolkit to enhance therapeutic engagement on acute mental health wards.

Design and participants: We describe a theory-driven approach to co-designing an intervention by adapting and integrating Experience-based Co-design (EBCD) with the Behaviour Change Wheel (BCW). Our case study was informed by the results of a systematic integrative review and guided by this integrated approach. We undertook 80 hours of non-participant observations, and semi-structured interviews with 14 service users (seven of which were filmed), two carers and 12 clinicians from the same acute ward. The facilitated intervention co-design process involved two feedback workshops, one joint co-design workshop and seven small co-design team meetings. Data analysis comprised the identification of touchpoints and use of the BCW and behaviour change technique taxonomy to inform intervention development.

Setting: This study was conducted over 12-months at an acute mental health organisation in England.

Results: The co-designed *Let's Talk* toolkit addressed four joint service user/clinician priorities for change: 1) improve communication with withdrawn people; 2) nurses to help service users help themselves; 3) nurses to feel confident when engaging with service users; 4) improving team relations and ward culture. Intervention functions included training, education, enablement, coercion and persuasion; 14 behaviour change techniques supported these functions. We detail how we implemented our integrated co-design/behaviour change approach with service users, carers and clinicians to develop a toolkit to improve nurse-patient therapeutic engagement.

Conclusions: Our theory-driven approach enhanced both EBCD and the BCW. It introduces a robust theoretical approach to guide intervention development within the co-design process and sets out how to meaningfully involve service users and other stakeholders when designing and implementing complex interventions.

Strengths and limitations of the study:

- To our knowledge, our study is the first to combine and implement a new theory-driven codesign/behaviour change process with service users, carers and clinicians in a mental health setting
- Our intervention development process was highly collaborative, with service users, carers and clinicians working together in equal and active partnership
- Our process provided a systematic and replicable system for reporting the behavioural mechanisms of action behind our complex intervention toolkit
- Although our process was highly collaborative, it was conducted at just one NHS site, which represents a possible limitation.

Background

Nurse-patient therapeutic engagement can broadly be described as the use of verbal and non-verbal interchange to improve a service users' mental health (1,2). Lack of high-quality engagement on acute mental health wards is strongly associated with increased rates of self-harm, violence, aggression, absconding and poor perceptions of inpatient care (3,4). Engagement may initiate and enhance the therapeutic relationship (5), which arguably has the greatest impact on treatment outcomes, over and above the specific interventions provided (6,7). However, nurses report high levels of acuity, reduced workforce, competing administrative duties and the nebulous nature of engagement as reasons for not engaging with service users (8,9,10). These factors also have a negative impact on nurses' job satisfaction (11), increasing the likelihood of burnout and leaving the profession prematurely.

Reports from service users suggest that wards are experienced as devoid from warm, respectful therapeutic interactions (12). Pharmacological treatments are prioritised over collaborative clinician-patient engagement, which leaves service users feeling stigmatised and alienated from their care team (13,14). Despite a recognition of the importance of collaborative care planning by clinicians, service users were often not involved in this process and felt as if they had no say in the trajectory of their care (15). Policymakers, researchers and patient advocacy groups globally have emphasised the importance of engagement in practice (16,17,18). However, lack of quality engagement is a longstanding, complex problem (19,20) and few nursing interventions to improve engagement are reported in the literature.

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One such intervention, predominantly implemented in the United Kingdom (UK) is Protected Engagement Time (PET). During PET, nurses devote a specified amount of time to regular engagement sessions with service users (21,22). PET originates from the Refocusing Model, which was a comprehensive series of interventions to improve inpatient services and reduce work strain on staff (23,24). The Refocus Model brought about improvements to the quality of care, staff sickness and costs, rates of absconding and self-harm (23). Following this, PET was adopted as a standalone intervention by mainstream policy (e.g.25), which resulted in its top-down implementation in many mental health services across England. Subsequent evaluations on both adult and older adult mental health wards found that whilst PET attempts to address nurses' opportunities to engage, it does not account for wider considerations about what is done within the engagement sessions (26,27,28). This may be because PET was intended to be used alongside other interventions, and its use as a standalone intervention stemmed from an atheoretical, common sense approach to implementation.

In response to PET's limitations, a Swedish study developed the Time to Talk (TT) intervention (29). TT is a form of PET, theoretically informed by two studies of everyday life on acute wards (30,31) and the Tidal Model – a holistic model of nursing care that promotes the exploration of service users' own narratives (32). In a qualitative evaluation of TT (33) service users reported that clinicians were more engaged after TT was implemented; however, their quantitative evaluation found no improvement in the quality of engagement as measured through the Caring Professional Scale (34). This mirrors evaluations of PET (26,27). Although PET and TT address nurses' opportunities to engage, they may not compensate for wider deficiencies in service provision such as poor supervision, clinical skills, and personal motivations (26,28), and neither were collaboratively developed with input from service users, carers and clinicians.

To better understand and enhance nurse-patient engagement in practice we previously conducted a systematic integrative review to develop a conceptual model of engagement (35). For high quality engagement to occur, the model suggests that nurses must employ techniques that encompass five "Principles of Engagement": 1) understand the person and their illness; 2) facilitate growth; 3) therapeutic use of self; 4) choose the right approach and, 5) emotional versus restrictive containment. The model drew upon behaviour change theory (36) to show that engagement is broadly influenced by both the service users' and nurses' capability, opportunity and motivation to engage. To address the limitations of previous interventions, we propose a collaborative, theory-driven approach to co-designing a complex intervention to improve the amount and quality of engagement on acute mental health wards. To do so, we have drawn from our model of

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engagement described above and adapted and integrated two existing approaches: Experiencebased Co-design (EBCD) (37,38) and the Behaviour Change Wheel (BCW) (36).

EBCD is a form of participatory action research which draws on user-centred design and user experience to improve healthcare services (37). The structured EBCD process, detailed in a freely available online toolkit (39), aims to meaningfully engage service users, carers and clinicians throughout a co-design process using observations, interviews and facilitated workshops. The Behaviour Change Wheel (BCW) and accompanying Behaviour Change Technique Taxonomy (BCTTv1) has amalgamated 19 behaviour change theories to create a framework that guides intervention development (36). It follows three phases: 1) understand the behaviour; 2) identify intervention options and 3) identify intervention content. At its core, the model suggests that capability, opportunity and motivation interact to create behaviours (COM-B) (40). The Theoretical Domains Framework (TDF) (41) is aligned in the model to the COM-B components and both are linked to nine intervention functions. The BCTTv1 is a taxonomy of 93 behaviour change techniques (BCTs). These 93 BCTs can be matched to the intervention functions to identify suitable behaviour change techniques (BCTs), which make up the active ingredients of an intervention (42,43). Figure 1 maps the BCW phases, methods and tools to the phases, methods and tools of EBCD and provides a theory-driven basis for the co-design of behaviour change interventions.

Figure 1 – Integrated Co-design – Behaviour Change model

Healthcare research and policy now recognise the importance of both co-designing interventions and using a robust theory to guide intervention development (44,45), but to date very few studies report on how to co-design complex healthcare interventions using a theory-driven approach. Currently there are no published studies that develop interventions using EBCD informed by the BCW. In response, we demonstrate the implementation of a theory-driven co-design-behaviour change process (Figure 1) that was used to develop a complex intervention toolkit for promoting nurse-patient engagement on acute mental health wards. We aim to:

- Describe a collaborative, theoretically driven approach to co-designing complex interventions;
- Demonstrate the implementation of this process to share learning with others;
- Develop a toolkit to enhance therapeutic engagement on acute mental health wards.

Methods

Design

This case study was guided by the UK Medical Research Council (MRC) complex intervention framework (46) and was theoretically driven by the content illustrated in Figure 1. The co-design process is reported in accordance with guidance for the reporting of intervention development studies in health research (GUIDED) (47) (Supplementary file 1). Ethical approval for the study was obtained from the London Fulham Research Ethics Committee (reference: 18/LO/2193). Participants gave written consent prior to being interviewed and again at the start of each co-design workshop. Posters that explained the purpose of the ward observations were displayed in common areas on the ward. Participation in observations was on an opt-out basis, to which nobody opted out.

Setting

The study was conducted with service users, carers and clinicians from one inner-London National Health Service (NHS) Foundation Trust in England, where the lead author had previously conducted exploratory work (5). The intervention ward has 18 beds and treats adults (18-65) experiencing an acute phase of severe mental illness. The ward is laid out along a corridor, with the nursing station and reception area at one end of the ward, the service user bedrooms running along both sides of the corridor and the service user lounge and day area at the opposite end of the ward to the nursing station. Service users are predominantly detained under the Mental Health Act (48). The ward consists of a multidisciplinary team of 20 clinicians, including eight registered mental health nurses (RMNs), seven health care assistants (HCAs), a peer support worker, an activities coordinator, an occupational therapist, a psychologist and a consultant psychiatrist. The nursing team works shift patterns from 0730-2130 or 2100-0800 and all RMNs and HCAs are involved in direct patient care including care planning, one-to-one interactions, close and hourly observations. The RMNs are responsible for medication rounds. The ward provides timetabled daily activities, run by the activities coordinator and service users attend weekly ward rounds led by the consultant psychiatrist and an RMN. This project began in April 2018 and complemented other organisational improvement work to re-implement PET.

Participants

The co-design team was recruited through:

- A convenience sample of service users and carers via: 1) face-to-face contact and posters at community mental health teams (CMHTs) and 2) face-to-face contact and email at service user advocacy groups connected to the participating NHS organisation;
- A whole population sample of clinicians on the participating ward were invited to take part via presentations, posters, email, and face-to-face meetings.

SM screened all potential participants, specifically looking for those who had, or had cared for somebody who had at least one inpatient admission at the organisation but was not currently experiencing a relapse. Eligible individuals were then guided through a written informed consent procedure. Figure 2 shows the recruitment process by type of participant and workshop attendance through the EBCD process. A total of 35 members were recruited to the co-design team including 15 service users, two carers, 10 RMNs, four HCAs, three psychological therapies clinicians and one student nurse. Just over half of the co-design team were female (54%) and just under half were from a Black, Asian and minority ethnic background (49%). Participants' ages ranged from 18-64 years. Service users had a variety of mental illnesses, including psychotic disorders such as schizophrenia and bipolar affective disorder (71%), personality disorder (7%), anxiety (7%) and eating disorder (7%).

Figure 2 – Recruitment process by type of participant and workshop attendance

Data collection and analysis

Data collection methods and processes were aligned to the EBCD phases and BCW stages contained in Figure 1 and informed by the aforementioned integrative review (35) these included nonparticipant observations and semi-structured interviews to gather service user, carer and clinician experiences, and feedback and co-design workshops to facilitate development of the engagement toolkit.

Non-participant observations and semi-structured interviews

SM (a mental health nurse, previously unknown to the study participants and trained in the application of the EBCD and BCW approach) conducted 80 hours of non-participant observations on the acute ward between the hours of 0730-1500 or 1330-2130, Monday through Sunday. Observations were performed in 15-minute intervals, beginning with the first nurse encountered

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and continued until all nursing staff had been observed. Fieldnotes were guided by Tyson and colleagues (49) and documented patterns of nurse-patient behaviour, nurse-patient dynamics, tone of voice, body language, potential influences on engagement and general ward atmosphere.

SM also interviewed 14 service users, two carers and 12 clinicians on a one-to-one basis at a location of their choice including university premises, offices at CMHTs or by telephone. All interviews were audio recorded and seven service user interviews were filmed in keeping with the EBCD approach. Interviews lasted between 30-80 minutes. A topic guide was followed, informed by our review (35), the non-participant observations and the COM-B/TDF domains (41,42). Interviews addressed participants' experiences of engagement, barriers and facilitators to engagement, and clarified assumptions made from the observations.

Full details of the non-participant observations and semi-structured interviews, including the inductive analysis of data to identify 'touchpoints' (emotionally significant points) of importance to the co-design team, are reported in a separate paper (50). A secondary deductive analysis of interview data, which is reported in this paper, was also undertaken to identify barriers to engagement. Deductive codes were based on the COM-B and TDF components of the BCW which were used as an *a priori* framework to analyse and thematically organise interview data. SM independently coded and themed the data using this framework. Extracts from both the filmed and audio-recorded interviews were also edited into a trigger film that was used to stimulate discussion at the feedback and co-design workshops.

Feedback and co-design workshops

Touchpoints and themes were shared at separate service user/carer and clinician feedback workshops and at a joint co-design team workshop. This ensured validity of the analysis, facilitated the joint selection of target behaviours based on the touchpoints, and allowed intervention options and content to be agreed. Seven co-design team meetings were also established to work on specific priority areas. Consensus was reached through facilitated discussions and consensus building exercises including emotional mapping (51) and affinity grouping (52).

Input was also sought throughout the co-design process from two mental health patient and public involvement (PPI) groups based at the participating organisation. An advisory group consisted of a service user representative, one clinician and clinical academic experts in (a) the EBCD methodology and (b) therapeutic engagement, respectively. The service user representative co-facilitated the feedback workshops with SM who also facilitated the joint co-design and co-design team workshops with the assistance of another nurse researcher trained in the BCW approach. Three co-design team

members wrote reflective accounts of their experiences of the co-design process and are co-authors of this paper.

Patient and public involvement

Service users and carers were at the heart of this research, being involved from conception, through execution and dissemination of this work.

Results

Here we present our theory-driven approach to co-designing the Let's Talk complex intervention toolkit. Our findings are organised under the three stages (and eight constituent steps) of the BCW guide, as shown in Figure 1.

Stage 1: Understanding the behaviours

Step 1: Define the problem in behavioural terms

Through previous research (5), our integrative review (35) and initial discussions with our PPI, advisory groups and the clinical service lead, modern matron and divisional medical director at the NHS organisation, the behavioural problem was defined as the absence of high-quality nurse-patient therapeutic engagement on acute mental health wards i.e. not using the Principles of Engagement identified in our review.

Step 2: Select target behaviour(s)

In keeping with the EBCD methodology, it was important to understand how service users and staff typically experienced engagement prior to the identification of relevant areas for behavioural change. Through observations and semi-structured interviews, the research team identified 28 touchpoints. Some examples of touchpoints were 1) I was left on my own and ignored; 2) my care was robotic and 3) As a nursing team we need to create better bonds with service users (full results in preparation to be published elsewhere).

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To ensure credibility, the touchpoints were discussed during two facilitated feedback workshops – one for service users and one for clinicians. In an emotional mapping exercise, participants were encouraged to identify improvement priorities based on their touchpoints and assign associated behaviours (see supplementary file 2 for breakdown of touchpoints into improvement priorities and associated behaviours). Participants then ranked their improvement priorities in a dot voting exercise and chose four priorities to take forward to the joint workshop (Table 1). The service user and clinician priorities were as follows:

Table 1 – Service user and	d clinician priorities for change
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Service user priorities	Clinician priorities
1) Nurse-patient communication needs to be	1) Improve the way we communicate with
improved	service users
2) Treat me like a human being	2) Improve the way that leave is communicated
3) Forgive and forget	3) Improve culture around response
4) Help me help myself	4) Improve the way messages are handed over within the team

At the joint workshop, facilitated discussion encouraged participants to consider the potential impact, likelihood of change, spill over effect and ease of measurement of all the improvement priorities and associated behaviours. An affinity grouping exercise was conducted and through this, four shared improvement priorities were identified and agreed:

- 1) Improve communication with withdrawn people
- 2) Nurses to help service users help themselves
- 3) Increasing nurses' confidence when interacting with service users
- 4) Improve team relations and ward culture.

Step 3: Specify target behaviour(s)

EBCD focuses on identifying participants' improvement priorities as a way of bringing about change that is meaningful to service users and clinicians (39). We used the BCW to examine each of the four

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joint improvement priorities. At the joint workshop, the co-design team formed into smaller groups with equal numbers of service users and clinicians. Each group completed a written exercise where they examined the joint priorities and associated behaviours in terms of who needs to perform the behaviour, what the person needs to do differently to achieve change and when, where, and with whom they will do it (Table 2) (See supplementary file 3 for example of written exercise).

Table 2 – Specification of behaviours for joint in	nprovement priorities
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Joint improvement	Behaviour specification			
priorities	What	Who	Where	When/with whom
Improve communication	1) Recognise who needs to engage	Nurses	Acute ward	When service users
with withdrawn people	2) respond in a timely and appropriate			require
	manner when engaging			engagement
Nurses to help service	1) Give practical advice 2) explain the	Nurses	Acute ward	During service
users help themselves	purpose of admission 3) understand the			user's admission to
	person 4) facilitate growth 5) give			an acute ward
	discharge support			
Nurses must feel	1) Have effective therapeutic	Nurses	Acute ward	When engaging
confident when engaging	conversations 2) articulate practical			with a service user
with service users	procedures in an understandable way			
	3) reduce anxiety when engaging			
Improving team relations	1) Ensure nursing team take care of each	Nursing	Acute ward	Throughout their
and ward culture	other 2) understand nurse-patient	team		shift with the
	dynamics on the ward 3) ensure a			nursing team and
	consistent response to service users			with service users

Step 4: Identify what needs to change

From our review and semi-structured interviews with service users, carers and clinicians, the research team identified 26 barriers to engagement and mapped them to the COM-B/TDF domains. The barriers were discussed with participants at the feedback workshops to ensure credibility. At the joint workshop participants matched the barriers to their four joint improvement priorities. The barriers related to each COM-B component are discussed below, with the corresponding TDF domains presented in parentheses.

Capability

Participants agreed that nurses often had limited knowledge and inadequate training in therapeutic engagement techniques (skills and knowledge):

"Although I've been doing this for almost five years it's like sometimes with certain patients you just don't know what to say...I wish there could be some training to understand that stuff." – RMN6

Nurses also felt that the very nature of having a mental health problem could make it difficult to engage, and while service users agreed that their mental illness and medication effects could negatively impact engagement (memory/attention/decision process), they were able to describe helpful engagement techniques that nurses could employ, even with the most acutely unwell people. This further highlighted the need to improve nurses' engagement skills:

"Sometimes you have a lot more patients who are unwell or sometimes they're less unwell, so engagement fluctuates week on week from that point of view" – RMN2

Opportunity

It was felt that there needed to be a cultural shift on the ward and within the organisation so that nurse-patient engagement activities were supported and valued in the same way as other tasks such as hourly observations or administrative duties (social influences):

"It was a numbers game, everyone's taking handover, another one's doing checks, some are on break...in an ideal world allocate friendly HCAs just to sit with patients." – SU7

There was unanimous agreement that lack of resources negatively impacted on nurses' ability to engage therapeutically:

"The problem for me lies on the number of staff, that is not enough..." – C1.

This created an untherapeutic ward environment where *"professionals would run around like mad rabbits not giving any attention to the patients."* – SU2 (environmental contexts and resources).

Motivation

Nurses felt that they could not always trust all members of their team to carry out the job in the right way. This created a feeling of helplessness for some nurses, which deterred them from engaging therapeutically (beliefs about capabilities):

"I became very aware that when there is an incident, I'm left on my own...I stopped trusting the team...I couldn't rely, therefore I needed to take a step back from the patients." – HCA2

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Service users were also deterred from approaching nurses for engagement because they felt nurses often did not understand their problems or would punish them if they asked for therapeutic engagement too often (beliefs about consequences):

"I kept myself to myself because even when I asked for simplest of things I was made to wait for ages so I would get frustrated, but if I showed frustration no doubt that would be on my notes and I would get set back." – SU4

As well as issues of trust, the ward staff felt as though their team were transient, with many longstanding nurses leaving to work elsewhere. This led to a lack of shared responsibility. Therapeutic engagement could easily *"fall through the cracks* – HCA1" and when poor quality engagement was witnessed, it was rarely followed up by a senior member of the team. This made some nurses feel they could not be bothered to engage:

"I mean to put it blunt; I know it sounds really bad...I can't be bothered." – RMN5

There was also a blurring of professional roles, where although nurses knew they should engage, they left it to other professionals such as the occupational therapist or activities coordinator:

"I can completely understand why nurses want separate roles because they would say you don't do our job so why should we do yours, but I do take people out on escorts and I do blur the boundaries there." – PT1.

When asked to give examples of nurse-patient engagement, many service users spoke about engagement with professionals other than nurses. This shows both the lack of engagement from nurses and the difficulty service users have in delineating between the nursing role and the role of other health professionals (social/professional identity).

There was a general sense from nurses that therapeutic engagement *"didn't always help people"* – RMN8 (optimism). This led some nurses to feel anxious about engaging therapeutically, particularly when they felt they did not have the required skills. When this was coupled with feelings of frustration at the perceived lack of managerial support, nurses reported feeling drained, burnt out and demotivated (emotions):

"One of the biggest problems is the management style which on paper, yes, it seems to be doing everything right, but in practice they have a very poor relationship with their staff and that does impact on performance...I just feel like no one cares about you, so why give up your time?" – RMN3

Stage 2: Identify intervention options

Step 5: Identify intervention functions

PPI and advisory group meetings highlighted that some of the terminology used to describe intervention functions would not be suitable to use with our participants. Words such as "coercion" can have negative connotations to mental health service users. Instead, practical examples that captured the essence of each intervention function were provided to participants at the joint codesign workshop. In a written exercise they were encouraged to use these examples to think about intervention functions that could address their four joint improvement priorities. Where possible we modelled these examples on illustrations from interviews with service users and staff. Where this was not possible, we developed examples from the BCW book (36) (Table 3).

Intervention function	Practical example given to co-design team
Education (Increase knowledge or understanding)	Service users meet with nursing staff once they have recovered and describe their experiences whilst on the ward *
Persuasion (Using communication to induce positive or	Have a poster on the ward that shows people happily engaging,
negative feelings or stimulate action)	with a message that reminds clinicians that engagement is part of their job, it is not "slacking off" *
Incentivisation (Create an expectation of reward)	Offer a prize for the ward that has the best patient feedback regarding interactions ^
Coercion (Create an expectation of punishment or cost)	At discharge, ask service users to provide feedback to the ward about the quality of interactions provided and hold staff accountable for this *
Training (Imparting skills)	Training program that enables nurses to role play with service users, so they gain skills on how to deal with service users' problems *
Restriction (Using rules to reduce/increase the opportunity to engage in target behaviour)	Nurses stop paperwork/admin during mealtimes and sit with service users and have a cup of tea or some food *
Environmental restructuring (Changing physical or social context)	Give service users cards that display different emotions and if they want to talk they can put the card on their door so nurses know to approach them *

Table 3 – Practical examples of behaviour change wheel functions given to co-design team

Have a therapeutic engagement champion who promotes
engagement and helps nurses to carry out group activities with
patients *
Have a ward diary for interactions that a member of staff is
responsible for each shift *

Key: * = example that came from participant interviews; ^ = example developed from BCW guide

Participants identified five intervention functions that were relevant to bringing about the desired change. These were 1) training; 2) education; 3) enablement; 4) coercion and 5) persuasion. Through discussions with senior management, the research team also identified restriction as a relevant function. The links between the COM-B/TDF domains and the intervention functions are shown in Table 4.

Step 6: Identify policy categories

The BCW includes policy categories which may help to support the delivery of an intervention. Through discussion with senior management, the research team identified communication/ marketing, guidelines and social planning as potentially relevant to facilitating our intervention. As such, the Principles of Engagement described in the introduction of this paper were included within Trust policy on therapeutic engagement and observations, and these principles will be directly linked with other components of the intervention, such as a training film described below.

Stage 3: Identifying intervention content and implementation options

Step 7 & 8: Identify behaviour change techniques and mode of delivery

Rather than provide participants with a long list of BCTs, the written exercise at the joint workshop encouraged them to design intervention strategies they thought relevant to each of the four priorities and its influencing factors. The research team retrospectively assigned BCTs to the participants' examples and selected further BCTs and intervention strategies not identified during the joint workshop. These were the basis for the development of the first intervention prototype.

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The prototype was further refined through an iterative process of email exchanges, telephone calls, a PPI meeting, seven small co-design team meetings and finally presentation of the work at an organisation wide acute care forum. As per the BCW guide (36) the APEASE criteria (affordability, practicability, effectiveness/cost effectiveness, acceptability, side effects/safety and equity) were used in an adapted form (see supplementary file 4) to stimulate discussion and ideas. These criteria ultimately informed the choice of intervention strategies for each improvement priority.

Fourteen BCTs were considered relevant to the *Let's Talk* intervention toolkit. Table 4 shows the link between each phase of the behaviour change intervention design process, the 14 BCTs and the intervention strategies and modes of delivery which resulted from the co-design process.

The *Let's Talk* toolkit consisted of four main components, linked to the co-design team's four joint improvement priorities:

- A 30-minute training film for nurses, delivered by service users and carers to be shown to nurses at the start of the intervention. Service users and carers discuss good and bad engagement techniques and personal accounts of their experiences of engagement whilst an inpatient, structured by our model of engagement.
- 2) An illustrated workbook called *My Conversation Companion* which includes guided exercises that nurses and service users can do together to help structure therapeutic conversations.
- 3) Signs attached to the outside of service users' bedroom doors to enable them to indicate, with a sliding panel, whether they would like engagement time or not. The signs are linked to the hourly nursing observation record, where each hour nurses will be required to record if a service user has requested engagement and if that request has been fulfilled. "Missed engagement" will be handed over at each nursing shift with the expectation that it is fulfilled that day. Observation records will be audited each month and feedback given to the nursing team. Additionally, an illustrated sign on the inside of service users' doors will encourage service users to use the signs if they want to engage.
- 4) Changes to nurses' daily routines, for example during handover, time will be made to checkin with the nursing team and offer additional support to any team member that needs it that day. Additionally, quarterly facilitated workshops will bring clinicians and service users together to discuss, reflect and improve practice.

Whilst conducting this work, the organisation was simultaneously discussing the potential addition of one extra staff member per shift. Our co-design team felt this would be beneficial to improving therapeutic engagement, however a decision on this is yet to be made. Through discussions with

	work at an acute care forum it was agreed that the <i>Let's Talk</i> intervention would support the						
1	elaunched implementation	on of PET wit	hin the organisation. I	Discussion with participants revealed			
1	hat they supported this a	nd considere	ed some form of PET es	ssential to support nurses to use <i>Let's</i>			
	<i>Talk</i> in practice. See Supp						
-	Table 4 – The behaviour c	hange interv	ention co-design proce	ess and components of the resulting			
I	.et's Talk intervention too	olkit					
Dahaviau		Intervention	BCTs	Intervention statesics/mode of delivery.			
Benaviou	ral analysis using COM-B/TDF (step 4)	Intervention functions	(step 7)	Intervention strategies/mode of delivery (step 8)			
	(step 4)	(step 5)	(000) 77	(
Priority 1: I	mprove communication wit	h withdrawn	people				
	Mar lada	1					
	Knowledge: - Nurses think service users	Education	Prompts/cues	Prompt/cues: Sliding door signs & accompanying			
	who stay in their rooms do	Euucation	Prompts/cues	supportive informational message on inside of service			
	not want to interact			users' door – acts as a cue for nurses to easily identify			
				service users who wanted to engage despite isolating			
				their bedrooms. Acts as a cue for service users to			
CAPABILITY				encourage them to ask for engagement if needed			
	Memory, attention,		<u>O</u>				
	decision:	Education	Prompts/cues	Prompt/cues: as above			
	- Service users' illness can						
	make it difficult to engage /						
	lose touch with reality						
	- Medications can make it	N/A	N/A	Addressed in priority 3			
	difficult to interact / retain		····				
	information						
	Social influences:						
	- Nurses must do	Restriction	Enablement:	Action planning: hourly observation record - each hour			
	observations within a set	Enablement	Action planning	allocated observation nurse records which service use			
	period, so focus on getting			door sign signals an engagement request and whethe			
	the task done rather than			that request has been met. If request not met			
	speaking to the service			immediately, the observation sheet prompts nurse to			

2 3	Behavioural	analysis using COM-B/TDF	Intervention	BCTs	Intervention strategies/mode of delivery	
4		(step 4)	functions	(step 7)	(step 8)	
5		((step 5)	((
6 7	OPPORTUNITY	Environmental context and				
8		resources:				
9		- Nurses feel they do not	Restriction	Restriction:	Restrictions & restructuring the social environment:	
10		have the time to	Enablement	Currently no BCTs for this	Protected Engagement Time – requiring nurses to stop	
11		interact/are allocated too	Enablement	function	duties that do not involve engagement for one hour each	
12 13		many patients to interact		Enablement:	day and use that hour to engage. This supports nurses to	
14		with all in one shift		Restructuring the social	use the <i>Let's Talk</i> toolkit with service users	
15 16		with an in one sint		environment		
10		- Nurses are busy so it is	Environmental	Environmental restructuring:	Prompts and cues: Sliding door signs & accompanying	
18		easy to miss service users	restructuring	Prompts / cues	supportive informational message on inside of service	
19		who are quiet			<i>users' door</i> – as above	
20 21		Beliefs about capabilities:				
21 22		- Nurses feel helpless	N/A	N/A	Addressed in priority 2 & 4	
23						
24		- Service users feel the	N/A	N/A	Intervention did not address this directly as it was	
25		nurses will not understand			thought that if nurses' behaviour changes and	
26 27		them if they talk to them			engagement is improved, this barrier will be mitigated	
28		Beliefs about				
29		consequences:				
30		- Nurses cannot be	Coercion	Coercion: Discrepancy between	Discrepancy between current behaviour and goal,	
31 32		bothered to interact as they	Education	current behaviour and goal	feedback on behaviour: hourly observation record –	
33		feel other tasks take		Education: Feedback on	Nursing team set goal of meeting all engagement	
34		precedence over		behaviour	requests each day. Allocated observation nurse records	
35		interactions			levels of engagement each hour. Levels of "missed	
36					engagement" fed back to nursing team via monthly audit	
37 38	MOTIVATION				and compared to set goal daily during nursing handover	
39					Prompt/cues: Supportive informational message inside	
40		- Service users are fearful of	Education	Education: Prompts/cues	service users' door – acts as a cue for service users to	
41		initiating an interaction			encourage them to ask for engagement if needed	
42 43		Social/professional				
44		identity:				
45		- Transient team so no	Education	Self-monitoring of behaviour	Self-monitoring of behaviour: hourly observation record	
46		sense of shared			- nurse in charge to check & record unmet engagement	
47 48		responsibility			requests and handover to next nursing team. Enables	
40 49					nursing team to monitor behaviour and create	
50					accountability within the team	
51		Emotion:				
52		- Nurses feel anxious about	Enablement	Enablement:	Enablement: Adding objects to the environment: Sliding	
53 54		approaching a person who		Adding objects to the	door signs – shows nurses that people who are in their	
55		stays in their room		environment	rooms want to engage	
56 57 58	Priority 2: Nurses to help service users help themselves					
59 60	CAPABILITY	Skills:				
60	CAFADILIT	541115.				

Behavioural a	analysis using COM-B/TDF (step 4)	Intervention functions (step 5)	BCTs (step 7)	Intervention strategies/mode of delivery (step 8)
	- Nurses say they are unsure	Training	Instruction on how to perform	Instruction on how to perform the behaviour: My
	what to say to service users		the behaviour	Conversation Companion workbook – provides nurses
	when they are unwell or			with short, guided exercises that can be done with
	have big problems			service users. This helps structure therapeutic
				conversations. This is supported further by priority 3
	Environmental context and			
	resources:	Restriction	Restriction & enablement:	Restrictions & restructuring the social environment:
	- The overall ward	Enablement	Restructuring the social	Protected Engagement Time – requiring nurses to stop
	environment is not set up		environment	duties that do not involve engagement for one hour each
	for quality interactions with			day and use that hour to engage. This will support nurs
OPPORTUNITY	service users			to use the Conversation Companion with service users
	- Nurses feel they do not			
	have the time for quality			
	interactions / allocated too			
	many patients to interact			
	with all on one shift		0	
	Beliefs about capabilities:			
	- Nurses feel helpless	Education	Education: prompts/cues	Prompts and cues: My Conversation Companion
				workbook – prompts nurses' therapeutic conversations
				by providing short, guided exercises to complete with
				service users e.g. working through service users' stresso
				or helping a service user identify their feelings from an
				emotions table
	Social/professional			
	identity:	Education	Education: reattribution	Reattribution: My conversation companion workbook –
	- Blurring of professional			encourages nurses to engage with service users and
	roles e.g. OTs & activities			reattribute this work as being part of their role
	coordinators do activities			
	groups, not nurses			
	Optimism:			
	- Nurses feel that they make	N/A	N/A	Addressed in priority 3
	an effort with service users,			
MOTIVATION	but it is not remembered or			
	appreciated			
	- Nurses feel that engaging	N/A	N/A	Addressed in priority 3
	is not always an effective			
	intervention for some			
	service users			
	Emotion:			
	- Nurses feel anxious about	Enablement	Enablement:	Adding objects to the environment – My Conversation
	approaching a person when		Adding objects to the	Companion workbook – provided to the ward to facilitat

Behavioura	l analysis using COM-B/TDF	Intervention	BCTs	Intervention strategies/mode of delivery
	(step 4)	functions (step 5)	(step 7)	(step 8)
	they are not sure what to			engagement between service users and nurses to help
	say to them			structure and guide therapeutic conversation
Priority 3: Nu	urses must feel confident v	vhen engaging	g with service users	
	- Nurses do not have the	Training	Training: Instruction on how to	Instruction on how to perform the behaviour: Training
	skills or knowledge to deal	Education	perform the behaviour, feedback	film shown to nurses – our review identified five
	-	Education		
	with service users'		on the behaviour, feedback on	principles for engagement, these are used in the film to
	problems		the outcome of the behaviour	educate nurses on how therapeutic engagement should
				be carried out in practice. Each principle is illustrated
	- Nurses say they are unsure		Education: Information about	through a video clip from the participant interviews
	what to say to service users		health consequences	giving personal examples of the techniques nurses use
	when they are unwell or			with them to fulfil each principle of engagement
	have big problems			
			0	Feedback on behaviour & outcomes of behaviour:
				Training film – the co-design team discussed the
				outcomes of both the lack of engagement and when
CAPABILITY				good engagement occurred e.g. "I think some nurses just
				see it as a nine to fivethey just want to get home and
				have dinner, you know? But considering how sick I was,
			· · ·	that lack of interaction made me feel very frightened." –
			O,	SU8
			4	Information about health consequences: Training film –
				Service users and carers discuss the mental health
				consequences of lack of engagement & good
				engagement e.g. "I felt like I wasn't being looked after by
				the nurses so I had to do silly things like I overdosed on
				tablets, I kept abscondingthere were a lot of problems
				associated with my illness the nurses didn't recognise." –
				SU2
	Memory, attention,			
	decision:			
	- Service users' illness can	Training	Training: Instruction on how to	Instruction on how to perform the behaviour: Training
	make it difficult to engage /		perform the behaviour	<i>film</i> – service users and carers discuss how nurses can
	lose touch with reality			engage despite illness and medication side effects e.g. "If
	,			you just learn to listen, that's quite often all somebody
	- Medications can make it			wants, but what nurses are trying to do is fix it and it
	difficult to interact / retain			doesn't need fixing, it just needs to be heard by the
	information			staffthey need to hear what that patient is going
				through and why they want to do what they want to do.
				Whether that's self-harm, suicide, a delusional belief,
				wine the that's seg-hurn, suicide, a delasional bellef,

Behavioural	analysis using COM-B/TDF	Intervention	BCTs	Intervention strategies/mode of delivery
	(step 4)	functions (step 5)	(step 7)	(step 8)
				whatever it is they need to understand that's a mental
				disorder that needs the help and support from the
				nurses" – SU11
	Environmental context and			
	resources:			
	- Nurses feel they do not	Training	Training: Instruction on how to	Instruction on how to perform the behaviour: Training
OPPORTUNITY	have the time to interact/		perform the behaviour	film - service users and carers discuss how engagemen
	are allocated too many			does not need to be a long, drawn out process e.g. "Th
	patients to interact with all			eye contact means everything. When the nurses say th
	in one shift			"Oh, they want us to sit there for an hour" it's not real
				truea nurse could really represent something for a
				patient, that one word, that one eye contact just to giv
				them reassurance that it's okay." – C1
	Optimism:			
		Education	Education: Feedback on	Foodback on bobaviour & outcomes of bobaviour
	- Nurses feel that they make	Education		Feedback on behaviour & outcomes of behaviour:
	an effort with service users,		behaviour, feedback on	Training film – service users and carers discuss momer
	but it is not remembered or		outcomes of the behaviour	they appreciated engagement with a nurse e.g. "I was
	appreciated			very against medicationbut one student nurse explai
				it to meher interaction was very positive, very one-to
			4	one, reassuring, so I took the medication orally and
				wasn't depo-injected which was a positive thing." – SU
MOTIVATION				
	- Nurses feel that engaging	Persuasion	Persuasion: Credible source	Credible source : <i>Training film</i> – filmed clips of service
	is not always an effective			users are used as a credible source to help persuade
	intervention for some			nurses that service users wanted to engage, and that
	service users			engagement is useful
	Emotion:			
	- Nurses feel anxious about	Persuasion	Credible source	As described above
	approaching a person who			
	stays in their room and/or			
	somebody they are not sure			
	what to say to			
Priority 4: Imj	prove team relations and	ward culture		
	Memory, attention,	Enablement	Enablement: Social support	Social support: Check-ins at handover – small changes
	decision:		(unspecified & practical),	will be made to nurses' daily routines, for example dur
	1			,,

Intervention strategies/mode of delivery

(step 8)

handover, time will be made to check-in with the nursing team and offer additional support to any team member

Social support: Reflective practice workshops - the ward

will attend quarterly facilitated workshops that bring clinicians and service users together to discuss, reflect

Restructuring the social environment: *Protected* Engagement Time – as described in priority 1 & 2

that needs it that day

and improve practice

BCTs

(step 7)

restructuring the social

Enablement: Social support

(unspecified & practical)

environment

2			
3	Behavioural a	Intervention	
4		functions	
5 6			(step 5)
7 8 9 10 11 12 13	CAPABILITY	- Nurses say they are tired	
14		Social influences:	
15 16		- The ward culture is not	Enablement
17		open to change	
18			
19 20 21		(D,
21 22	OPPORTUNITY	- The overall ward	Restriction
23		environment is	Enablement
24		untherapeutic	
25			
26 27 28 29 30 31			
32		Beliefs about capabilities:	
33		- Nurses feel helpless	Enablement
34 35		Numero de continunt	
35 36		- Nurses do not trust	
37		everybody on their team to	
38		do the job the right way	
39		Social /professional	
40 41		identity:	
41		- Transient team so no	Enablement
43		sense of shared	
44		responsibility	
45	MOTIVATION		
46 47		Emotion:	
48		- Nurses feel frustrated at	N/A
49		the lack of managerial	
50		support	
51 52 53 54 55 56 57 58		- Nurses feel burnt out	Enablement
59 60			

ll ward	Restriction	Enablement & restriction: Social	Restructuring the social environment: Protected
nt is	Enablement	support (unspecified & practical),	Engagement Time – as described in priority 1 & 2
tic		restructuring the social	
		environment	Social support: Compassion Champion - while not part of
			the current Let's Talk toolkit, the co-design team would
			like to do ongoing work around implementing a
			Compassion Champion who advocates for both staff and
			service user wellbeing within the organisation
ut capabilities:			
el helpless	Enablement	Enablement: Social support	Social support: Check-ins at handover, reflective practice
		(unspecified & practical)	workshops & Compassion Champion - as described above
not trust			
on their team to			
he right way		2	
fessional			
		(
team so no	Enablement	Enablement:	Social support: Check-ins at handover, reflective practice
ared		Social support (unspecified &	workshops & Compassion Champion – as described above
ty		practical)	
el frustrated at	N/A	N/A	Intervention did not address this directly as it was
managerial			thought that by implementing measures such as PET,
			check-ins at handover, reflective practice workshops & a
			Compassion Champion, nurses would feel supported
el burnt out	Enablement	Enablement: Social support	Social support: Check-ins at handover – as described
		(unspecified & practical),	above
		restructuring the social	
		environment	Restructuring the social environment: Protected
			Engagement Time – as described in priority 1 & 2

Discussion

The delivery of high-quality nurse-patient therapeutic engagement is a complex issue that requires input from service users, carers, clinicians and researchers alike. Interventions to improve engagement must be multifaceted and encompass service users', carers' and clinicians' capabilities, opportunities and motivations to engage. We used the methodical and evidence-based framework of the BCW to guide intervention development within a co-design process. This enhanced the process by supporting its "intrinsically desirable qualities" (53) with a robust theoretical underpinning that facilitated a full analysis of existing barriers and behaviours among its principal stakeholders. Although Larkin and colleagues (54) suggest that it may be unrealistic to expect co-design participants to generate solutions to longstanding problems within a short space of time, supporting participants' ideas with a systematic and methodical theory of behaviour change may help mitigate that limitation.

Recent literature encourages a systematic, comprehensive, and transparent approach to intervention development (40). However, many behaviour change interventions are poorly defined and do not use consistent language to describe their mechanisms of action (55,56) making it difficult to pinpoint what did and did not work, which also reduces the ability to compare such interventions (41). The BCW enabled us to identify, understand and describe the mechanisms of action behind *Let's Talk* which is likely to both improve its effectiveness (57) and enable us to review and refine intervention targets after preliminary testing. It also emphasised the importance of addressing nurses' capability, opportunity, and motivation to engage. Previous interventions such as Protected Engagement Time focus predominantly on the opportunities nurses have to engage, but do not consider whether a nurse may be capable or motivated to engage. This may explain why evaluations of PET have not shown improvements in the quality of engagement (58). To our knowledge this is the first intervention aimed at improving engagement to be developed and presented in this comprehensive, systematic, and transparent manner.

Although systematic, the BCW approach may be considered somewhat prescriptive. This can clash with the underlying principles of co-production and co-design, which demand democratic, innovative and creative techniques (59,60). The concept of co-production in mental health was not commonplace even five years ago (61). Traditionally, professional knowledge had a higher status than service users' lived experiential knowledge (62,63). Despite some notable exceptions (e.g., 64,65), service user participation in research was, and often still is tokenistic, with participants having little influence over defining the problems or required changes (63,66). It was essential that

our process acknowledged, explored and addressed these power differentials so as not to reinforce these entrenched ideals.

Academic language and terminology can preserve power differentials and compromise user and clinician participation (67,68). People who suffer from mental health problems experience effects that can negatively impact cognition and concentration, often exacerbated by medications (69). The use of overly technical language may disproportionally affect people from this group and may lead to exclusion and disempowerment (70), which mirror some of the alienating experiences faced whilst an inpatient on acute wards (e.g., 71). While the COM-B model uses relatively simple terminology (40), the language used to describe the intervention functions was particularly problematic. Intervention functions such as "coercion" and "restriction" may have triggered difficult emotions for some of our participants. These words describe negative ward experiences for example when clinicians coerce service users into taking medication (72), or when liberties are restricted due to treatment under the Mental Health Act 1983 (48). This was also true of the clinicians who participated in our study. Suggesting that they lacked "skills" or "knowledge" was likely to alienate them from the process and make them feel devalued.

To ensure fidelity to the underlying principles of co-design we therefore tailored the BCW approach to the needs of the co-design team. The research team found that providing practical examples of each intervention function, using language from the service users', carers' and clinicians' interviews, was a suitable way of adhering to the principles of co-design and using evidence-based theory in a non-alienating, confirmatory way. Although APEASE criteria were not considered to contain triggering terminology, some of the language was overly technical which also risked alienating codesign team members. The research team therefore translated the APEASE criteria into more accessible language. Furthermore, the co-design team were encouraged to design their own intervention content based on the behavioural analysis. The research team retrospectively assigned BCTs and confirmed these with the co-design team. This adhered to the underlying principles of codesign by foregrounding service user experience (rather than privileging academic knowledge over experiential knowledge), whilst also creating an intervention that could be clearly and methodically described through evidence-based theory and language.

Reflective accounts from three of our co-design team support the steps taken by the research team to ensure an inclusive, participatory process. Whilst the potential for experiential reflections to trigger difficult emotions was anticipated, team members' expressed anxieties were soon 'quashed' by a 'safe and secure' environment in which members 'never felt pressured or judged'. This allowed the service users, carers and clinicians 'to support each other on an equal basis and share a common

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goal'. The opportunity to share personal experiences emerged as an important dynamic across the three reflective accounts. It was variously described as 'a privilege', and an 'incredibly moving' and 'powerful' experience that allowed their expert knowledge to be used 'to implement new models of care and improve quality standards' that 'would make a real difference'. Consequently, these codesign team members described an 'enjoyable' and 'rewarding' process that engendered feelings of pride and empowerment. One member referred to it as a 'life changing' event that promoted selfesteem and self-awareness, and another reported the development of reflective skills. Notable also was the wider outreach and consultation that members undertook through liaison with professional colleagues, services users and carers in various institutional and community arenas, which mirrored their experience of the co-design process. This allowed stakeholders to express any concerns, ask questions and provide feedback. In turn, this led to 'product refinements to make the workbook more accessible and easier to read'. As well as personal impact, these team members described inter-personal benefits including 'feeling (more) engaged with mental health professionals' and managing to 'engage in some really good work' with patients. They were also optimistic about the likely impact of this work moving forward. They sensed that service users and clinicians were *'inspired'* by their work and believed the workbook would have 'a ripple effect...and help create a cultural change within the organisation'. Each of the reflective accounts is provided in full in supplementary file 7.

Beresford (73) argues that frontline clinicians can also be a marginalised group whose voices are often excluded. It is also vital to consider the needs of the service provider whilst embarking on participatory work (74). We implemented several facilitative measures such as providing backfill money so clinicians could attend the feedback and joint workshops and offered flexibility with participation in the small co-design team work e.g., emailing instead of face-to-face meetings and piggybacking staff meetings. However, enabling clinicians to participate equally was challenging. Unfortunately, organisational structures such as shift patterns and staffing levels impacted on clinicians' ability to fully participate. Regular staff meetings or reflective practice groups were also not in place. When given the opportunity to participate, clinicians were motivated, and meaningful participation was possible during the feedback and joint workshops. However, without organisational support structures to provide clinicians time to undertake the ongoing co-design work, much of the prototyping and iterative development of the intervention components were undertaken by the service users. This is a common issue evident in co-design studies in both mental health and general settings (75). There is a need for healthcare organisations to reconfigure their services so clinicians can meaningfully participate in such endeavours and encourage a sense of joint ownership over the work.

Although the process was highly collaborative and involved service users, carers and clinicians to varying degrees, it was conducted at just one NHS site, which represents a possible limitation. Transferability of our processes to other settings cannot be guaranteed. However, to our knowledge, this is the first time the BCW has been translated for use with participants who have mental health problems and used within an integrated co-design-behaviour change process. This new and novel approach will require further testing to ascertain whether it is suitable and translatable to other intervention development processes. Given that participants were a selfselecting, motivated sample of clinicians, service users and carers, their views may not be representative of all patients and clinicians in the organisation. During the final stage of codesigning Let's Talk the global COVID-19 pandemic took place. We continued our co-design activities remotely, however, a planned quasi-experimental pre-post-test using a structured observational tool (49) had to be postponed. The tool examines the amount, type (e.g. interactive, individual, verbal, non-verbal or solitary) and quality (e.g. positive feedback, praise, smile, ignoring, reprimand, discouragement, neutral behaviours) of nurse-patient interactions (49). Pre-test data on one control and one intervention ward was collected in April – June 2019 and we plan to collect post-test data when we are able to do so and publish the results of this study.

Conclusions

This paper has described the implementation of a new theory-driven co-design/behaviour change approach used to develop the *Let's Talk* intervention toolkit. It offers tools that others may use, or adapt as necessary, to implement the approach in their settings. It also describes the behavioural mechanisms behind the *Let's Talk* intervention toolkit to improve the amount and quality of nursepatient therapeutic engagement on acute mental health wards. Our paper makes a timely and novel contribution to further both participatory methods and behaviour change theory. The approach enhances EBCD by introducing a robust behavioural change theory to help guide the development of a complex intervention. In turn, our participatory approach also enhances the BCW by setting out a practical guide on how to meaningfully involve service users and other stakeholders when designing complex implementation interventions.

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Declarations:

Consent for publication

NC, VD and CS have consented to their reflective accounts being used within this manuscript.

Availability of data and materials

All data generated or analysed during this study are included in this published article and its accompanying supplementary information files.

Competing interests

All authors declare they have no competing interests.

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Authors' contributions

SM conceived of the study, secured the research funding, facilitated the co-design process, analysed the data, contributed to designing intervention components and wrote the manuscript. GR, AS and VT participated in the design and coordination of the study, contributed to the analysis and helped to draft the manuscript. NC, VD and CS participated in the co-design process, contributed to designing intervention components and wrote reflective accounts for the manuscript. All authors read and approved the final manuscript.

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