The SAINT a guided self-help intervention for people with intellectual disabilities

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Abstract

Introduction

This paper introduces the SAINT (**S**elf-**A**ssessment and **INT**ervention) a guided self-help intervention for the treatment of mild depression in people with intellectual disabilities

Method

The study used a single case experimental design and adopted quality frameworks specific to the approach to describe the participants and to standardise the study. The aim was to examine the acceptability and effectiveness of the SAINT on reducing symptoms of anxiety and depression. Semi structured interviews were conducted to record user experiences and were using a framework analysis approach. Attendance at sessions was also monitored.

Results

Nine people receiving guided self-help using the SAINT demonstrated a decrease in symptoms for both intervention phases for either depression or anxiety, with four showing a decrease in mean symptom scores in both intervention phases for both depression and anxiety. Those with a history of affective disorders and those with moderate intellectual disabilities showed improved symptom scores during both intervention phases.

Summary and Conclusion

The idea that the SAINT can be feasibly implemented in routine clinical practice was broadly supported with the positive outcomes relating to symptom reduction and acceptability. From the feedback received the SAINT is tolerated well by participants and viewed positively by those using it and those who have supported people in its use.

Introduction

Evidence suggests that people with intellectual disabilities (ID) are more likely to suffer from mental health problems and health inequalities than those in the wider population (Cooper et al. 2007, Cooper and Simpson 2006, Emerson and Baines 2010, Emerson et al 2012; Smiley et al. 2007, and Whitaker and Read 2006). Mental disorders including depression can be difficult to recognise in this group, which can affect subsequent diagnosis and treatment (Lunsky and Palucka 2004). Whether people with ID can benefit from psychological treatment approaches has been a matter of debate for over 40 years; and although the availability of psychological treatment is increasing for people with ID, it is still often the case they are excluded from mainstream mental health and IAPTs services (Burke 2014). The provision of CBT and other psychological treatments for adults with ID appears to have developed in line with an increased understanding of the mental health needs of this group of people (Hatton, 2002). It is now increasingly accepted that people with ID can benefit from a range of psychological approaches e.g., psychoeducational groups for psychosis, (Crowley, Rose, Smith*, et al*, 2008; Kirkland, 2005), depression, (Lindsay, Howells & Pitcaihly, 1993), anxiety and cognitive behavioural anger treatment (Taylor, Novaco, Gillmer*, et al*, 2002; Taylor, Novaco, Gillmer*, et al*, 2005) and CBT for Sex offenders (Sex Offender Treatment Services Collaborative – Intellectual Disabilities (SOTSEC-ID), 2010).

However there is limited evidence on the effectiveness of psychological therapies for people with ID. A meta-analysis of psychological treatment for people with ID (Vereenooghe and Langdon 2013) reported that group-based interventions had a moderate but smaller treatment effect than individual-based interventions, with CBT found to be effective for both anger and depression. However there is a need for further clinical trials and outcome studies in this area to further investigate and increase our understanding of this area. Historically, effectiveness has been difficult to establish in part due to the variation in administration of psychological treatments. The failure of a number of studies to consider individual needs and preferences has called into question the results of previous studies that have dismissed the use of psychological treatments for people with ID following the report of poor treatment outcomes (Thompson Prout & Nowak-Drabik, 2003).

There are a number of issues to consider when trying to improve treatment outcomes, such as the adaptation of materials and the therapist's awareness and understanding of ID (Hatton, 2002; Wilner, 2009). This process is known as "developmental adaptation" and involves the modification of language, goals, strategies and tasks (Thompson Prout and Nowak-Drabik, 2003). It is important to remember that this not always necessary for those with mild ID (Dagnan, Chadwick & Proudlove, 2000), and some adaptations can be negative, for example

relying on proxy based reporting at the expense of self-report which has traditionally been ignored to inform assessment and outcomes (Fujiura, 2012). Mason, (2007) put forward five factors that are believed to influence the outcome of psychological therapies for people with ID:

- The perceived effectiveness of clinicians on psychological therapy
- Individual clinician competence
- Service resources; number of clinicians
- The severity of the client's disability
- The diagnostic overshadowing bias

The aim of this current study was to establish proof of concept i.e., can Guided Self Help (GSH) be used by people with ID and is it effective in reducing symptoms of depression? Although GSH has been endorsed by the UK Government as an effective means of combating mild depression (Department of Health 2001), and is defined as "… a self-administered intervention designed to treat depression, which makes use of a range of books or other self-help manuals derived from an evidence-based intervention and designed specifically for the purpose…" (National Collaborating Centre for Mental Health 2009, p182). GSH is typically advocated as an intervention to promote positive mental health or for the management of less severe disorders, or to alleviate symptoms and/or prevent deterioration that may need to be treated using more intrusive methods such as medication. Furthermore, compared to other treatments, those receiving GSH may be less likely to suffer deterioration in mood following treatment (Williams et al. 2013). GSH offers a means of equipping individuals with the skills to be more independent in managing their mental wellbeing, thus reducing dependence on services (Lovell et al. 2008).

Using CBT approaches is the most common and effective form of GSH (National Collaborating Centre for Mental Health 2009) (184-187) and Williams et al 2013). In spite of an increasing number of studies reporting on the effectiveness of GSH there is little evidence that it is used with or is being used as a treatment for people with ID. This may be for a number of reasons, including the fact that the GSH materials currently available often require a level of cognitive functioning that unintentionally excludes many people with ID. This paper reports on a GSH intervention and treatment resource called the Self-Assessment and INTervention pack (SAINT), which is specifically designed for people ID.

Ethics

A favourable ethical opinion was received on the 23rd August 2008 (granted 20th August 2008) (08/H0809/43), from the Bexley and Greenwich Ethical committee. A substantial amendment to the study was submitted and approved by the South London REC office 5 on the 7th April 2011.

Methodology

Study design

The study used a reversal single case experimental design (SCED) (A-B-A-B) to examine effectiveness and proof of concept. To achieve this a mixed group of individuals with ID were recruited i.e., those with a pre study diagnosis of depression and those with sub threshold symptoms of mood disorders. The SCED was designed to last 16 weeks (4 weeks for each phase ABAB). Quality frameworks devised by Horner et al. (2005) and (Kratochwill et al. 2010) were used to inform the design of the SCED including management of phases, number of data points, internal, external and social validity.

Recruitment

The participants were recruited from a number of areas including specialist mental health in-patient, community mental health and residential services, for people with ID across the south east of England. Of the 22 people that were identified to take part in the study and who met eligibility criteria; seven were withdrawn by clinical teams or those supporting them; either before or in the first few weeks of the study. This usually occurred following deterioration of mental state and in some instances because of reconfiguration of services. Of the 22 identified, 18 started the study, with 15 participants completing the SAINT over one or more baseline and intervention phases *male* = 7, (46.7%) (*M* = 44.3 years old, *SD* 19.47, range 18-68), *female*=8, (53.3%), (*M*= 31.38, *SD* 9.9, range 21-46). In total twelve participants completed all four phases. The three that started and did not complete were all withdrawn on the advice of their clinical team following deterioration in their mental state.

Qualitative methods were used to record user experience, 16 participants who expressed an interest in giving feedback were approached to undertake a semi-structured interview, of these nine agreed to participate. The interviews were conducted by a Nurse Researcher who analysed the data from the interviews using a framework analysis approach.

Inclusion/exclusion criteria

All participants were aged 18 or over. ID was defined as being known to ID services or identified as having an ID by mental health services. A clinical diagnosis or sub threshold symptoms of mood (affective) disorders F 30-39 was required along with the ability to provide consent. Those not meeting these criteria or who lacked capacity to understand the project were excluded.

Of the 15 participants, all had a history of affective symptoms. In terms of primary diagnosis six (40%) had a clinical diagnosis of depression, four (26.7%) had autism spectrum disorder (ASD) and four (26.7%) had psychosis. Of the six who had a diagnosis of depression only one met the study criteria for current depression, i.e., a score of 13 or over on the GDS-LD. In addition, a further two participants who had not previously been identified as being depressed met the study criteria for depression. In terms of level of ID, 11 (73%) were recorded as having a mild ID and four (26.7%) met criteria for a moderate ID

The intervention

The SAINT is a manual based GSH approach that is designed to be used by people with ID with or without support. It is designed so it can be administered by non-therapists e.g., health professionals or graduates. It is designed to help people with ID to self-report from a list of feelings and emotions that have the potential to impact negatively on their mental health. The SAINT has a diary section to record both positive and negative experiences. This is preceded by a number of coping strategies to address adverse mental health needs identified from the feelings list. There is also an accompanying instruction manual for both those using it and anyone supporting them. Training was given to all participants and offered to carers or others supporting them.

The GSH sessions using the SAINT were facilitated by Registered Nurses (Mental Health or Learning Disabilities field). The sessions occurred weekly and lasted from 30 minutes to an hour. This variation was to take into account individual issues of understanding, memory, concentration and reporting. This format remained consistent across study settings. The sessions focussed on the person's mental health and their ability to identify feelings and potential flashpoints that could negatively impact on their mental wellbeing. Once identified the use of and choice of coping strategies to address these issues within everyday scenarios were discussed. The sessions took place every 7 days, +/- 2days, to allow flexibility and choice. Participants were encouraged to seek support (if available) between sessions from friends or carers. Prior to starting the intervention (A**B**AB), teaching on how to use the SAINT was conducted by the facilitators, and a training manual was given to reinforce

learning. Following the first intervention phase the resources were removed from participants. Weekly visits still took place during the non-intervention phases. This was to ensure that any increase or decrease in symptoms was due to the intervention and not just as a result of having a regular visits. During these phases the SAINT was replaced by offering time to engage in general conversation unrelated to mental health. During all phases the participants received all other treatments prescribed as usual. As part of treatment as usual, changes to medications and other treatments occurred as clinically indicated for the duration of the 16 weeks of the SAINT intervention. In the study design, duration of illness, current treatment, and previous response to treatment (responsivity, vs treatment-resistance) were not considered.

Outcome measures

The Glasgow Depression Scale-Learning Disabilities (GDS-LD) (Cuthill et al. 2003) and Glasgow Anxiety Scale –Intellectual Disability (GAS-ID) (worries section) (Mindham and Espie 2003) were administered weekly before each GSH session took place, and during the weeks the intervention did not take place. The SAINT was scored by self-report i.e. participants answering yes or no to the statements on the feelings list. This was compared with the GDS-LD and GAS-ID to establish reliability and validity (Chaplin et al. 2013). Visual analysis was used to analyse the SCED. As recommended for this method, the following areas related to visual analysis were considered: level (mean), trend, variability, overlap, immediacy of the effect, and consistency of data patterns across similar phases, (Fisher et al. 2003, Barlow et al. 2009, Kazdin 1982, Kennedy 2005, Morgan and R. 2009, Parsonson and Baer 1978, Kratochwill et al. 2010)

Acceptability of the SAINT was assessed by attendance during the intervention sessions (A**B**A**B**) and through feedback from the semi structured interviews. The interview examined how people had used the SAINT e.g., what levels of support had they received, their feelings on its strengths and weaknesses and its ease of use. All interviews were taped and transcribed and analysed using framework analysis (Srivastava and Thomson 2009). Additionally, field notes and comments received from participants and those supporting people using the SAINT were considered. Attendance during the intervention sessions was also recorded

Results

GDS-LD and GAS-ID Outcomes

In total 12 of the 15 participants completed all four phases (ABAB), one completed three phases ABA and two completed two phases AB. Of the 12 participants who completed the full 4 phases of the intervention, 9 (75%) demonstrated decreased depression symptom scores

and 3 (25%) had decreased anxiety scores in both intervention phases compared to the preceding baseline and non-intervention phases. Of the 3 (20%) who met the study criteria for depression, one completed all four phases and showed a reduction in symptoms of depression in both of the intervention phases and a reduction in anxiety in the final phase. Of the other two; one completed three phases and a showed decreased symptom by the post intervention phase (ABA). The remaining case was withdrawn after two phases following a relapse of psychosis (see tables 1 and 2 for results of those meeting and those not meeting study criteria for depression). There was also a reduction in the number of problems identified using the SAINT from six participants (50%) in both intervention phases. In terms of psychopathology, of those who completed the four phases; particpants with a history of affective disorders 8 (66.6%) showed the most consistent improvement. Of the three participants who failed to show a reduction in symptoms, none had previously received a clinical diagnosis of depression.

ENTER Tables 1 and 2 around here

User experience with framework analysis

The SAINT offered a positive experience to the majority of participants. The intervention was tolerated well and overall attendance in the intervention weeks in the study was 86.4% (over eight sessions). In terms of ease of use two participants reported difficulties using the SAINT between sessions. This highlights the need for adequate support especially for those who are less able. In terms of support between sessions this appeared to vary by study location, e.g., within inpatient services, the intervention was more likely to be seen as part of the treatment programme. This meant that it was more likely that participants would receive the support and guidance requested, whereas those being supported in the community were more likely to use the SAINT privately or not seek support.

A number of the interview transcripts analysed were brief and reflected the difficulty many of the participants had in expressing and articulating themselves in situations where they may feel they are being 'tested'. A series of iterations was used to bring sub-themes together however this was partly affected by some of the limited responses of participants' experiences.

From the interviews a number of key themes were identified which were considered under the following four headings: personal reflection, barriers to use, the utility of the SAINT and potential improvements to SAINT. See figure 1, supporting the idea that the SAINT can be feasibly implemented in routine clinical practice.

ENTER Figure 1 around here

Discussion

There are no previous studies of this nature so comparison is difficult. However, the study was able to demonstrate that people with ID could use GSH and that its use brought about a reduction of symptoms as evidenced by replication of effect with single participants.

The study used mixed methods bringing together qualitative and qualitative techniques, which are increasingly looked upon as a continuum (Niglas 2006). The use of SCED to examine symptom reduction and semi structured interviews to record personal experience and gauge acceptability has added extra dimension to the study. Single subject research is often dismissed due to limited insights into its purpose, the range of designs and the belief that studies involving one person prove nothing. SCED should not be confused with case studies and/or case series, which usually report the results of treatment but lack a scientific approach. As in this study SCED can be used to address a broad array of questions such as feasibility, proof of concept, hypothesis testing and building. The Medical Research Council guidelines (Medical Research Council 2008) (which informed the course of this study) endorse SCED as a legitimate experimental intervention. SCED offers certain advantages over a Randomised Controlled Trial e.g., being able to provide information on the variability of participant responses to an intervention in real time rather than estimating its effect across a whole group. SCED examine the effect of an independent variable on the dependent variable. Unlike RCTs, the SCED lends itself to modification by adjusting and changing of the independent variable. The aim is to improve the intervention profile through comparative intervention of the evidence base by recruiting individually, SCEDs are a cost effective way to provide evidence by identifying and defining those who are felt most likely to benefit from the intervention. This is important when informing future RCTs. The consistency of delivery of GSH is highly variable as to what constitutes a treatment episode (Williams et al. 2013). In the study participants received up to four sessions although a number of participants did not return after one session. SCED aims to establish the effectiveness of an intervention over a period of time on a group or individual. To do this it makes observation and recordings over a series of baseline and intervention phases. How this is achieved is dictated by the study and the independent variable is introduced in a planned way within designated phases whilst the dependent measure is collected repeatedly throughout the study. The design will vary in complexity from basic comparison to complex crossover designs. This is because there is no set standard. In SCED participants act as their own control and examines whether positive results can be maintained or improved following a break and reintroduction of the

intervention when the initial A-B phases are repeated. This ABAB design was preferred to a moving baseline design given the heterogeneity of the participants in terms of location, stage of recovery, level of ID, comorbidities and primary diagnosis. What the design allowed was the examination of a number of sub groups in an attempt to establish which groups might have the potential to benefit from GSH. Visual analysis was used to examine both within and between data patterns during the baseline and intervention periods and is still the preferred and accepted method for smaller studies not leading themselves to statistical analysis. The strength of visual analysis is that it is able to identify if a functional relationship exists between the introduction of an intervention and reduction in symptoms and replicate effects across individuals or groups of individuals (Lane and Gast 2014). In this study the use of SCED afforded the opportunity to not only examine proof of concept but also allowed those meeting criteria for depression to be examined as a sub groups.

Acceptability was assessed via attendance at sessions and semi-structured interviews. These were analysed using framework analysis methodology. During the study a number of considerations were made to improve engagement and provide consistency to how the SAINT was used by staff and understood by users. Part of this was to provide a positive training experience to familiarise participants with both the SAINT and concept of guided self-help. The training sessions were developed and a training manual produced reflecting the content. Copies of the book were given to both participants and carers attending training. (A training book has since been published along with the SAINT manual and resources, Chaplin et al , (2014). Originally the training was to be delivered to participant and carer groups over a day; however, problems with services releasing staff to attend meant that often training was completed on a case by case basis. This type of situation is consistent with earlier research that has suggested recruitment to group training can be problematic (Chadwick et al. 2001). Delivering training to individuals made it a more personal experience and afforded the opportunity of addressing individual concerns, which may have been missed in a group setting. The emphasis on training and information before the start of the intervention may have helped account for the high attendance rate for sessions. The complexity of effective GSH interventions also lends itself to evaluation using qualitative methods, to help our understanding of how people use and experience interventions (Khan et al. 2007). Participant feedback was captured and analysed using framework analysis methodology. This allows a systematic approach that lends itself to scrutiny at all stages of the process and also allows the testing of a priori assumptions. Like other qualitative methodologies framework analysis is concerned with finding order, patterns and structure to record and make sense of people's experiences. Traditionally this has meant that studies have been biased and often not included those who have difficulty articulate their experience due to cognitive and social impairments.

There is still debate as to whether qualitative methods are a legitimate research tool in people with ID. Many of the arguments used against participation have also been applied to other groups where people may have an issue expressing themselves. In spite of this with adaptations to how information is provided and responses received there is no reason why people with ID should not take part in qualitative research. The transcripts from the interviews in this study provided evidence of independent thought and speech, demonstrating participant choice and not being suggestible to the comments of the interviewer. In terms of satisfaction with the intervention, critical comments and constructive criticism from participants highlighted a number of key issues. Individual experiences of the intervention overall were varied. For the participants who lacked support, the potential impact of the intervention and subsequent experience may not have been fully realised. However in practice regardless of the level of support received between sessions, there was variation on how the SAINT was used. For example some participants would identify and record their feelings using numbers in the diary as is suggested in the training manual whilst others would use the diary to record their feelings and coping strategies in more detail and not always stick to writing a corresponding number relating to their feelings. The personal feedback received from the semi structured interviews offered a valuable insight into the SAINT's utility in practice. One limitation of the sample was of the feedback was provided by just 9 of the 16 participants. All participants who gave feedback reported that they enjoyed or benefited from the experience of using the SAINT, and that it was easy to incorporate within existing routines. Furthermore a number of people continued to use the SAINT following the conclusion of the study. Although many participants were unable to expand on answers given during the interviews, or did not wish to talk of their experience formally, they were able to give both positive examples of how they used the SAINT and offer constructive criticism on areas that would benefit from improvement Although a number of responses to questions were brief, they did include both positive and negative responses. The negative responses received were an important part of validating the questionnaire, as it suggests that the response is genuine and not as a result of the person being suggestible or acquiescing. Negative feedback included answering questions about self-harm and that the SAINT could be difficult to understand sometimes in terms of knowing what to do. What was encouraging was that the negative comments occurred in the context of a reported good overall experience. On balance participants viewed the experience of using the SAINT as positive and worthwhile. Two participants in particular gave considerable feedback, including one person who was inspired by the experience, and was supported by care staff to write a book and presentation on his experiences of using the SAINT and how it could be used to benefit others. The positive experiences and reported improvements of those using the SAINT was not always apparent in the visual analysis, which focussed on symptom reduction rather than

other benefits such as increased engagement with staff. A positive side effect of the intervention was reports from some staff that after supporting people to use the SAINT they felt they knew more about and better understood the person they were working with. In terms of looking to improve the SAINT, two participants did find it slightly complicated, which highlights the need for adequate support especially for those with lower levels of functioning.

In terms of effectiveness 75% demonstrated decreased depression symptom scores in the first study when compared to the preceding baseline or non-intervention phases. What the results suggest is those with depression or significant affective symptoms appear to benefit most. Of those who failed to improve in terms of symptom reduction; none had previously received a clinical diagnosis of depression.

A limitation of the interpretation of results is that participants had reviews in medication or non-medication treatments during the intervention. Participants were also subject to array of other treatments for depression and other mental health problems such as occupational therapy. Ideally participants should only be receiving GSH in terms of intervention or a strategy would need to be in place to control for treatment change or additional interventions. Although participants act as their own controls in SCED the addition of other interventions will limit what can be inferred.

It was the case that the participant group were not primarily clinically depressed or anxious. The GDS-LD only identified three participants who met the study criteria for depression and only one of these showed a reductions of depressive symptoms in both intervention phases, whilst the other two did not complete the intervention. This does not mean that GSH is not an effective intervention for depression in people with ID. It probably has more to do with the complexity of clinical presentation. This demonstrates that prescribing GSH needs careful consideration and it is offered to those likely to benefit from it at the time of referral, as is the case in other psychological therapies such as CBT. We know from the results both participants with mild and moderate ID were able to use the intervention. The majority of those who failed to complete the intervention, excluded themselves or were withdrawn either as a result of additional mental health issues affecting behaviour and concentration. Although there is inconsistency of effect for the intervention in terms of meaningful clinical improvement; the study was able to demonstrate proof of concept.

Although there is no literature to speak of relating to people with ID and GSH, there are a number of studies that illustrate the use self-help techniques as part of an overall treatment approach in a number of different scenarios e.g., relaxation (Taylor, Novaco, Gilmer, *et al*,

2002) and an intervention for fire setting (Clare, Murphy, Cox, *et al*, 1992). However, there is still uncertainly in the absence of published evidence, on the effectiveness of using self-help strategies as the main treatment component. Part of this is due to the increased expectations put on the individual to essentially take control and manage their treatment with brief input from a facilitator.

Conclusion

The clinical challenges posed by people with ID and mental health problems are gaining wider recognition. However there is still more work to do to reduce health inequalities that prevent access to treatment enjoyed by the general population. More support and greater awareness from clinicians and commissioners is required to ensure that this group of people with complex needs benefit from the full range of mental health services. The idea that the SAINT can be feasibly implemented in routine clinical practice was broadly supported with the intervention piloted in a number of residential and clinical settings. The SAINT demonstrated good promise by decreasing mean scores for the majority of participants. There are issues as to the levels of support individuals need, this would need to be examined further in any future study, to evaluate its contribution to the intervention. Initial feedback suggests that the SAINT is tolerated well by participants and viewed positively by those who have supported people in its use between sessions.

The SAINT demonstrated that its use can help people with ID to manage their mental health. This is important if we are committed to partnership working and people being equipped to make their own and join in with decision making. The accessibility of the materials developed ensured ease of use and was easily understood by the current support networks. This inclusive approach allowed people not only to engage and benefit from the approach but to gain more independence in managing their mental health.

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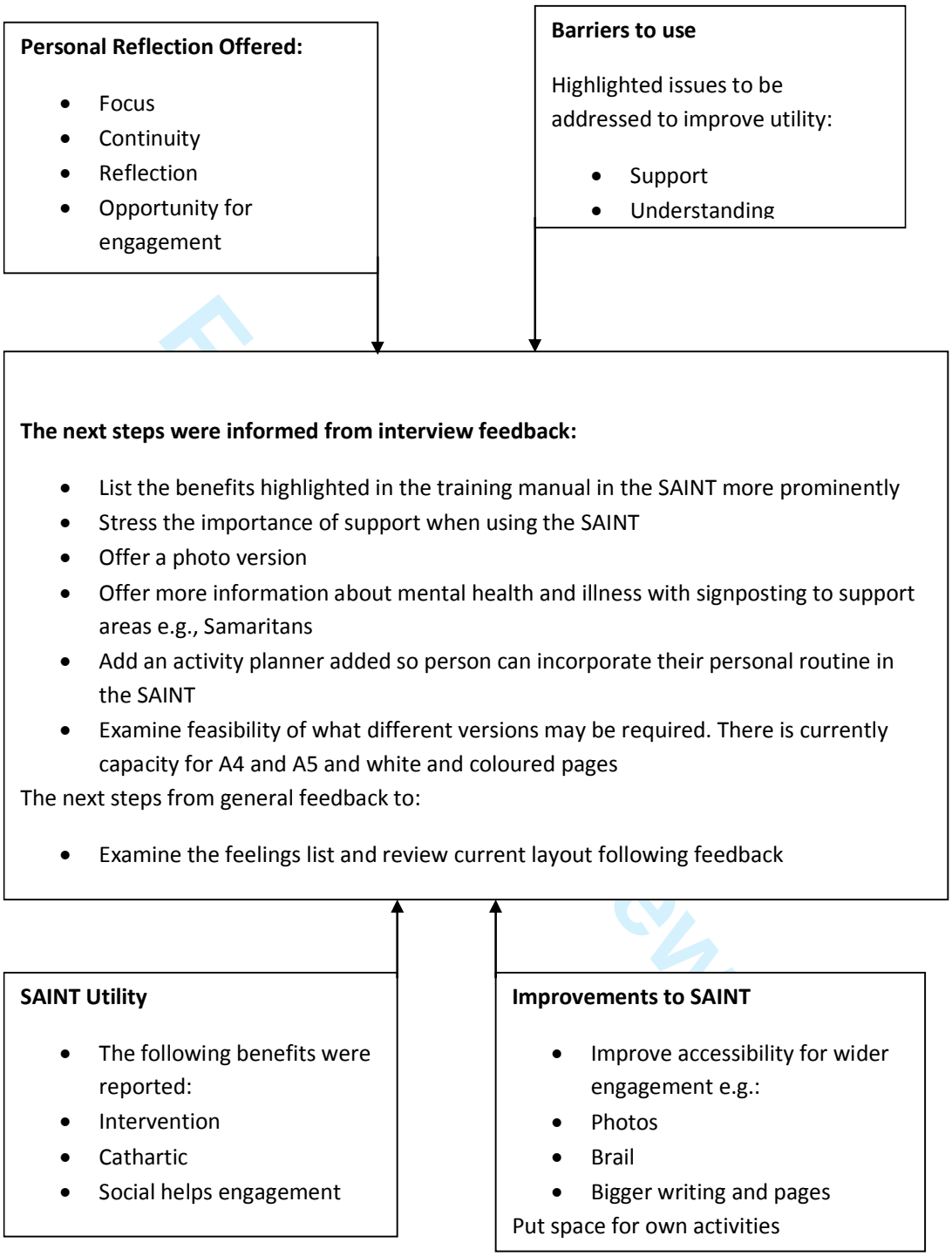

Figure 1: Participant opinions of the SAINT following participation

This figure illustrates the stages and outcomes of Framework analysis, which considered four areas: personal reflection, barriers to use, the utility of the SAINT and potential improvements to SAINT. The middle box outlines proposed ways forward.

Table 1: Mean phase symptom scores for participants not meeting caseness for depression

	GDS-LD					GAS-ID			
ID no.	A	B	A	B		A	B	A	B
Reduction of symptoms of depression in both intervention phases									
1*	5.5	3.7	5.5	5		3	2.3	3	3
3	2.3	0.7	2.5	2.3		2	2	2.5	0
4	2.5	2	0.7	0.3		2	1.7	1.2	0.7
5*	5.8	5	5.7	5		2.8	5	1.5	3.8
7*	6	4.3	8	5		5	3	5.5	3
8*	3.8	1.8	3.2	1.5		3	2.3	1.7	2.3
10	12	16.5	17	13		10	11	13	11
14	9.3	5.3	6	5.5		3	0.3	3.2	1.8
Reduction of symptoms of depression in one intervention phases									
6	3	2.8	2	4.5		2	2.8	0	1.8
2*	3.8	10	11	8.3		10	10	11	8.5
11	3	2.8	2	4.5		2	2.8	0	1.8
Those not completing the intervention									
15	12	9	NC	NC		8	5.5	NC	NC

**Participants having a diagnosis of depression recorded in case notes*

Table 2: Mean phase symptom and SAINT scores for participants meeting caseness for depression GDS-LD 13 or >

GDS-LD					GAS-ID				
ID no.	A	B	A	B		A	B	A	B
Reduction of symptoms of depression in both intervention phases									
13	18	17	18	16		10	11	10	9.3
Those not completing the intervention									
12*	13	13.8	12	NC		10	9.5	8.5	NC
9	15	0.8	NC	NC		15	16	NC	NC

**Participant having a diagnosis of depression recorded in case notes*