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Can positive behavioural support (PBS) assist STOMP medication challenge?

Abstract

Purpose: This study aims to investigate if Positive Behavioural Support (PBS) can be an effective alternative to medication, and can aid medication reduction in people with a learning disability, autism or both who are prescribed psychotropic medication for behaviour thought to be challenging. **Background:** STOMP is an initiative supported by NHS England which aims to reduce inappropriate prescribing of psychotropic medication, i.e. antipsychotics used for challenging behaviour in the absence of a documented mental health diagnosis. PBS has been described as the first line of intervention for behaviours which challenge (NICE, 2015) and has been highlighted as a non-pharmacological alternative to medication. **Design:** A two-group, experimental design was utilised. Both groups were considered for medication reduction. The experimental group of 25 people received input from a specialist PBS team, while the control group of 29 people underwent unsupported medication challenge. **Findings:** There was a significantly higher success rate for medication reduction and discontinuation when PBS assessment and intervention was provided as an alternative to medication. **Practical implications:** This study indicates that providing PBS is associated with decreased medication and if replicated should become standard practice for specialist teams. Further investigation into the specific components of PBS that aided medication reduction and discontinuation is required.

Originality/Value: This is the first study to investigate the effect of PBS on medication reduction in patients prescribed psychotropic medication for behaviour thought to be challenging.

Keywords: Positive behavioural support, medication reduction, PBS, STOMP, quality of life, pharmacist independent prescriber

Background

Stopping over-medication of people with a learning disability, autism or both (STOMP) is a project supported by NHS England aimed at reducing the inappropriate prescribing of psychotropic medication to manage behaviour that is deemed to be challenging in the absence of a documented mental health diagnosis (Branford et al 2018; NHS England 2016). The current project was launched in 2016 following the report into the Winterbourne View care home which highlighted concerns related to the use of medication in this way (Department of Health 2012), in particular the off label and poorly evidenced use of psychotropic medication. Historically, little guidance has been available to guide the appropriate use of psychotropic medication (Tyrer et al., 2008; Deb et al., 2007, 2009).

A report by Public Health England in 2015 (PHE, 2015) showed that 30,000-35,000 prescriptions are issued *each day* to people with a learning disability and/or autism for psychotropic medication to manage behaviours, rather than as treatment for a serious mental illness. A UK population-based cohort study identified that people with a learning disability who presented with challenging behaviour were more than twice as likely to receive antipsychotic medication as those who did not have any behavioural challenge (Sheehan et al., 2015).

In 2015 NICE (NICE, 2015) published a guidance document detailing how behaviours which challenge should be more appropriately managed placing the reliance on non-pharmacological methods as the first line intervention, with medication being considered only when other measures have not been successful in keeping the person safe.

Behaviours which challenge is not a diagnostic criterion unlike serious mental illness. Diagnosis of serious mental illness is more difficult in people with a learning disability and there exists a potential for ambiguity between a presentation of serious mental illness and behaviours thought to be challenging which may lead to initiation of an inappropriate care pathway.

These guidance documents demonstrate a shift in thinking away from reliance on medication and towards non-pharmacological interventions. Such interventions can be initiated for all new cases of behavioural challenge but does not affect those

people who historically have been in receipt of psychotropic medication without any specialist behavioural input.

One non-pharmacological approach is the use of positive behavioural support (PBS), which is described in NICE guidance for individuals with behaviours which challenge (NICE, 2015). PBS is a framework to support understanding of the function of a person's behaviour. It focuses on working collaboratively with the individual and people around them, including family members and other carers, to make changes to environments to better meet their needs. There is also an emphasis on teaching people new skills so they can communicate their needs in a different way. The overall aim of PBS is to improve the quality of life of the individual and those around them (Gore et al., 2013).

There is little guidance for the ideal process of medication reduction and discontinuation. Much of the available literature highlights the success rate of medication reduction without any consideration of alternative intervention (Ahmed, 2000; Branford, 1996; de Kuijper et al., 2014). In all these studies medication was reduced and removed without any other intervention being considered. Some studies have identified factors related to unsuccessful medication challenge which include environment, staff opinion, staff understanding of psychotropic medication and effect of physical ill health (Ramerman et al., 2018; de Kuijper et al., 2013, 2014; de Kuiper & Hoekstra, 2018). Many of these factors are considered within the PBS framework and intervention pathway described below.

Given the historical reliance on medication, and the absence of any well-evidenced alternatives, we decided to explore the effectiveness of using PBS support to aid medication challenge for patients identified as suitable for a STOMP medication challenge. A control group was provided by a cohort of patients who had their medication challenged without the support of PBS practitioners.

Aims

- To investigate whether PBS can effectively support medication reduction
- To assess the likely success of medication reduction with and without PBS involvement.
- To explore whether PBS support can influence the reluctance to reduce

medication

Method

A two-group experimental design was utilised. Both groups were considered for medication reduction. The experimental group received input from a specialist PBS team, while the control group underwent unsupported medication challenge.

Participants

In total, 54 patients took part in this study. 25 patients were in the experimental group and received PBS support alongside a medication challenge. 29 patients were in the control group and received unsupported medication challenge. Patient characteristics are shown in Table 2 but did not form part of the statistical analysis.

[Table 1] Patient characteristics

All patients were referred to the pharmacist independent prescriber for medication review. Referrals came through the PBS specialist, the PBS arm of the study or directly to the pharmacist from a General Practitioner or Care Team requesting a psychotropic medication review, the Non-PBS arm. The pharmacist allocated equal numbers to each arm of the study with four patients in the PBS arm being subsequently excluded due to changes in environmental factors prior to the work being initiated. Once each patient had been identified for a STOMP medication review they were referred to the pharmacist independent prescriber for challenge to medication. Patients in each arm of the study were required to meet the pharmacist's inclusion criteria, shown in Table 2 based on the level of professional confidence and competence.

[Table 2] Inclusion Criteria

Procedure

The PBS team and the pharmacist independent prescriber designed a PBS-STOMP clinic model based on the existing PBS pathway, utilised by the team, together with

the opinion and understanding of the patient and their care staff in relation to psychotropic medication and behavioural challenge.

The pharmacist met with each patient and their care team, including paid and family carers, to discuss and potentially challenge the psychotropic prescription. Five patients received more than one psychotropic medication and it was agreed that one type would be challenged at a time rather than multiple challenges. Once agreement for challenge had been agreed by all parties the pharmacist began the medication challenge process following a similar design in both arms of the study.

Table 3 shows the clinic process utilised by the pharmacist in all reviews with patients in both arms of the study. Both arms were collaborative, with key care staff and family members being invited to the review with the patient.

In the PBS arm, behavioural data were collected by the care team and collated by the PBS practitioner. These data were presented at each PBS review to aid decision making in relation to medication in addition to the factors in Table 3.

Within the PBS arm there was weekly support from the nurse practitioner in between the medication reviews. In the Non-PBS arm there was no support available between appointments. The PBS input continued beyond the end point of medication challenge for up to three months.

[Table 3] Clinic Process

Timescales and percentage dose changes were flexible and person-centred and not uniform in either arm of the study. As a minimum, the pharmacist agreed to meet the patient and people responsible for supporting their care approximately every 4-6 weeks unless there were mitigating factors dictated by the care team such as changes to the patient's environment.

Following agreement to initiate the challenge to medication, the pharmacist continued with the reduction process, with the full agreement of each patient and their care team. Dose reductions were variable with the pharmacist setting the arbitrary milestones of 25%, 50%, 75% of initial dosage to record specific achievements. These stages are detailed in Table 4 (the number of steps to achieve these milestones were flexible and varied in both arms of the study and dictated by

the patient and carers).

[Table 4] Stages of medication reduction

Materials

In the PBS arm a variety of assessments and interventions were implemented based as needed after full functional behavioural assessment. The first stage of a PBS pathway includes functional assessment to ascertain the reason why a person may be behaving in a particular way. This is typically conducted by a Community Nurse with additional PBS training and/or experience. Other members of the Multi-Disciplinary Team contribute to the assessment process, including support workers, speech and language therapists, occupational therapists and psychologists to ensure a holistic understanding of a person's needs. Data from assessment were analysed and synthesised to help develop a working formulation of a person's behaviour and the behaviour of those around them. A variety of interventions were used in the study based on functional understanding of an individual's needs. Intervention packages typically offered to the PBS arm of the study included:

1. The development of a Behaviour Support Plan (BSP). The purpose of a BSP is to provide a description of how an individual's environment should be redesigned to reduce challenging behaviour and develop alternative behaviours (Chaplin et al., 2014). BSPs are aimed at direct carers and provide detailed instruction and prompt to guide carer behaviour.
2. Carer training. Behaviours which challenge can be complex so it is often necessary to provide training or coaching to direct care staff and families (MacDonald & McGill, 2013). This training typically involves helping others understand challenging behaviour, as well as supporting people to understand and implement the BSP.
3. Active support. This is an intervention that was designed to help staff working in small community homes for adults with Learning Disabilities (Totsika et al., 2008). The approach equips staff to support meaningful engagement in activities and relationships by people with intellectual disabilities (Koritsas et al., 2008).

The PBS practitioner(s) involved were responsible for conducting the assessment, and working collaboratively with a patient, their family and carers to negotiate and implement the most helpful interventions. The PBS practitioner also collected data to monitor the effectiveness of any interventions, and reformulate a patient's needs when necessary. The data collected was used during the pharmacist's review to open discussions with the patient and their families/carers and to support decision making around medication reduction.

Results

1) Reviews

[Figure 1]

Figure 1 describes the overall differences in STOMP challenge and medication reduction when supported by a PBS specialist compared to no such support (Non-PBS). The number of patients were similar in each arm, with 25 in the PBS group and 29 in the non-PBS group. All were reviewed by the same pharmacist using similar referral criteria and review process. Within the PBS arm 130 reviews were carried out compared to 78 in the Non-PBS arm. Each PBS-supported patient attended a mean of 5.2 reviews compared to 2.7 without PBS.

2) Initiation of medication reduction

Of the 25 people supported by PBS 92% (n=23) agreed to initiation of medication challenge at the first pharmacist review. Without that support the initiation rate was 41% (n=12) and many patients required multiple appointments before agreeing to medication challenge. This association between intervention and initiation was significant, $\chi^2 = 15.09$, $p < .01$. At the end of the study 15 people had still not agreed to medication challenge despite education and support from the pharmacist and PBS practitioner. Only one patient supported by PBS refused to initiate the medication challenge compared to 14 in the non-PBS arm.

3) Discontinuation of medication

In the PBS arm, 15 (60%) patients successfully completed the discontinuation of medication compared to 15% without. A further 8 patients (32%) are actively undergoing STOMP medication challenge, in the PBS arm, without yet reaching an agreed final stage of challenge. The overall success rate for all patients in the study cannot yet be fully ascertained but could be between 60% and 92% of participants.

Restarting or increasing medication

In the PBS arm, one patient needed medication to be reintroduced or increased following discontinuation or reduction compared to eight patients in the non-PBS arm. The one PBS patient who needed medication to be restarted following successful discontinuation was due to a perceived increase in behavioural challenge and no PBS supported patients needed a medication increase following a reduction.

. There was a significant association between the use of PBS and prescribing, $\chi^2 = 16.6124$, $p < .01$. Inspection of the frequencies reveals that PBS was associated with significantly more patients having their medication stopped, while non-PBS patients were more likely to have their medication increased following an initial reduction

Type of medication Challenge

[Figure 2]

Figure 2 shows the type of medication that was challenged throughout the process. All were antipsychotics thereby gaining continuity of prescription type. More than half of the prescriptions were for risperidone (52%). All other antipsychotics were atypical in nature with no patients being referred to the clinic on a typical type of medication. It was not the intention of this study to look at specific medications.

Discussion

This study set out to ascertain whether PBS supported the success of STOMP medication challenge compared to medication challenge without any additional intervention.

In the literature review, most historical studies had focused on medication reduction unsupported by other interventions. The most recent published work, by de Kuijper et al. (2014), the successful discontinuation rate was 61% two weeks after stopping medication falling to 46% three months later. The PBS group demonstrated a similar discontinuation rate to that found by de Kuijper (61% de Kuijper vs. 60% in this study) although a further 32% of patients are still undergoing medication reduction and this success rate may considerable increase. A difference to the Dutch study is that after three months of discontinuation the success rate with PBS support had reduced slightly to 56%. This is a smaller decrease compared to the Dutch research (56%:46%) This improvement compared to recent studies points to a measurable impact of PBS support

The data show a difference in medication challenge medication when supported by PBS methods and when not. At each stage of the process, initiating a reduction schedule there is a difference between the two groups, pointing to greater success with the support of PBS.

1. Initiation of a reduction schedule

Patients and their care team were far more likely to agree to medication challenge when supported by the PBS practitioner than when unsupported. The reasons underpinning the difference in likelihood to initiate a reduction schedule between the two arms of the study may be multifactorial but points to the role of PBS in challenging and exploring the concerns to medication challenge through education and support. The full behavioural assessment may also help support teams and family members to better understand their patient's needs before initiating reduction. This may lead to more effective management strategies being implemented as well as a better understanding of behavioural function and the ruling out of physical causes and environmental factors.

The PBS pathway highlights STOMP education at the point of initial assessment and the theme develops throughout the work of the team. The focus enabled discussion in the early stage of contact and the skilled practitioner would then decide the point of referral for a STOMP medication challenge having completed the educational element of the work. This could have contributed to the majority of patients agreeing to medication challenge at the pharmacist's first appointment. The pharmacist then

excluded much of the background and educational awareness and could focus on the medication challenge process and measures of success and concern.

In the Non-PBS arm the patient and their support staff were educated about STOMP at their first appointment. In all cases they had no awareness about STOMP and mentioning medication challenge drove significant concern in both the patient and their care team. Where medication challenge was considered it was with a specific reason such as side effect burden or concern in relation to long term medication usage. The issue of STOMP awareness and education relating to medication risks and benefits could be seen to play a part in the success of medication challenge.

2. Subsequent reductions

The data demonstrates that more patients continued with the reduction process when supported by PBS practitioners. In 70% of reviews, with PBS support, the reduction schedule continued as planned with a further reduction being initiated at subsequent appointments. In the remaining cases the reduction was delayed by other factors such as seasonal variations in presentation, changes in staff or physical ill health requiring intervention such as pain, infection or poor bowel management plans. This often delayed but did not stop the process. No patient had to be excluded due to significant physical ill health or worsening of mental wellbeing. These would have been immediate exclusion criteria for this study. There is always a risk that medication challenge, especially of an antipsychotic, may unmask a previously undiagnosed serious mental illness.

In the Non-PBS group many patients believed that the initial reduction was also the final one and that STOMP reviews stopped with this initial reduction. It became difficult to shift this thinking in the care team who displayed the same initial anxiety about reduction as when it was first discussed. The educational input and ongoing support from the PBS practitioner could have contributed to patient and carers agreeing to additional medication challenge. At each review the PBS practitioner discussed the data collected in relation to the behavioural challenge which the pharmacist used to drive prescribing decisions. A pictorial representation of behavioural data, often in graph format, demonstrated the impact of medication challenge as well as other interventions made by the PBS practitioner. This allowed a degree of reassurance for the care team regarding the impact of medication

reduction and a greater understanding of the function of behaviour i.e. meeting a patient's need. For example, in one case of successful medication challenge, the frequency of behaviours increased as the severity diminished. In this case staff understood that the function of the behaviour was communicative in nature and they responded differently to meet an unmet need. This understanding enabled the medication challenge to continue with renewed confidence from the team.

3. Medication discontinuation

The number of patients progressing to full discontinuation was also more evident in the PBS-supported group. The use of behavioural data at each stage of the process allowed for a clear understanding of impact of medication reduction together with non-pharmacological input to support each individual. The progress to discontinuation was smoother, less likely to involve a change in reduction rate and more likely to succeed. In most of the successful cases of discontinuation the PBS practitioner would remain involved with the team on a weekly basis, being there to provide reassurance, support and a functional understanding of behaviour. Each prescribing decision within the PBS arm was driven by behavioural data recorded by the staff team and collated by the PBS practitioner. This data collection continued beyond discontinuation to provide a degree of reassurance as the patient acclimatised to being medication free. This continued for at least three months after discontinuation which could prove invaluable to the patient and their care teams. It was evident that prior to initiation and at the point of discontinuation were the times of greatest concern about the process. Having a trusted support practitioner to oversee both these critical points in the process could have contributed to more successful outcomes. During this time frame only one patient required medication to be restarted which reduced the overall discontinuation rate from 60% to 56%. This compares the reduction in discontinuation rate of 61% to 46% in de Kuijper et al.'s (2014) study. This therefore indicates that use of PBS is associated with better medium term outcomes in relation to medication discontinuation. Further work should explore the outcomes over a longer period of time to determine whether the reductions/discontinuation of medication is maintained.

4. Medication restarting or dose increased

In the study only one patient required a medication increase or restart when

supported by PBS. The team remained as support for the care staff for a minimum of three months post discontinuation or cessation of the medication challenge. This compared to 66% when not supported by PBS. This element of continuing support and focus on behavioural intervention could have allowed successful medication challenge to be maintained and to support care teams to focus on continuing non-pharmacological intervention well beyond medication discontinuation.

Limitations and future research

Although the data presented in this study indicate that PBS involvement may support medication reduction, it is unclear which specific components of the framework are helpful. While it appears that a functional understanding of behaviour, and an alternative intervention means that medication reduction is likely to be more successful than the unsupported model, this study alone is unable to draw those conclusions. One could hypothesise that PBS input means that families and staff feel supported to look at alternatives, and are provided with awareness and education regarding a functional understanding of behaviour. Full consideration of staff attitudes and concerns, together with an environmental assessment and the exclusion of physical ill-health factors, may lead to increased chances of successful medication challenge. Further research is needed to understand what specific elements or interventions have the greatest significance on successful medication challenge.

This study did not set out to measure quality of life improvements linked to successful medication challenge as it was beyond the scope of this paper.

Although we believe that our results are robust, a larger sample would have helped strengthen our claims. A sample size calculation indicated a sample of 105 would have been sufficient (with a confidence level of 95% and a margin of error of 5%). Future studies should therefore aim to recruit a larger participant group and make greater use of statistical techniques to explore differences between the two arms of the study.

The work does not capture how much input was given to each person before the pharmacist began to reduce medication. Similarly, it does not capture the type of intervention(s) initiated to support the patient prior to the reduction starting. More

work will be needed to consider the impact of specific interventions and type of support. Similarly, it would be beneficial to capture the type of staff and carer concerns that PBS specialists are able to overcome prior to prescriber involvement.

Conclusion and Clinical Implications

This study indicates that PBS support could enable more robust medication challenge from initiation through each stage of reduction to successful discontinuation and medication-free maintenance. It is possible that PBS support could overcome patient and staff reluctance through education, assessment and functional understanding of behaviour and management of environmental and physical health factors.

Competing Interests

None declared

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REFERRAL CRITERIA

• Stable behaviours	No worsening of baseline frequency, severity and duration if data available
• Stable physical health	Well managed physical health without significant physical health co-morbidity
• Stable epilepsy	No more than TWO anti-epileptics and well controlled seizure activity
• No mental health diagnosis	Historical or current
• Psychotropic medication	Antipsychotics, antidepressants, mood stabilisers ¹ , anxiolytics and hypnotics excluding anti-epileptics just for epilepsy effects not seizure activity

Table 1. Inclusion referral criteria to the PBS-STOM¹Anti-epileptics being used for mood

Table 2. The pharmacist process for all reviews PBS and Non-PBS

STRUCTURE	WHAT	NOTES
1) EDUCATION	<i>STOMP Awareness</i>	General information, background, aims
2) OPINION	<i>Person, care team and family members</i>	Expectations and concerns of medication challenge Key factor was consistency
3) ENVIRONMENT	<i>Staff turnover, staff education, home stability, seasonal factors e.g. Christmas</i>	Key factor stability and optimal treatment with clear care plans
4) PHYSICAL HEALTH	<i>Known co- morbidities, current treatments, medication, epilepsy care plans, bowel, sleep and dietary charts</i>	Data-driven decision making
5) MEDICATION		Grading system to quantify changes
6) ACTIVITY LEVELS	<i>Benefits in relation to target behaviours Side effect burden using the GASS To access changes in planned activity and engagement</i>	Assessed using bespoke activity record forms

Table 3. Stages of medication challenge with the requirements for success

STAGE	REQUIREMENTS	
INITIATION	Agreement to start a medication reduction programme on first meeting with the pharmacist	
REDUCTION STAGES	25% 50% 75%	Maintained for at least 4 weeks to be classed as successful
DISCONTINUATION	Full removal of the medication for at least 4 weeks	
RESTART or INCREASE	A dose increase or medication being restarted after 4 weeks or more at the reduced level	

Figure 1. STOMP reviews and reduction stages

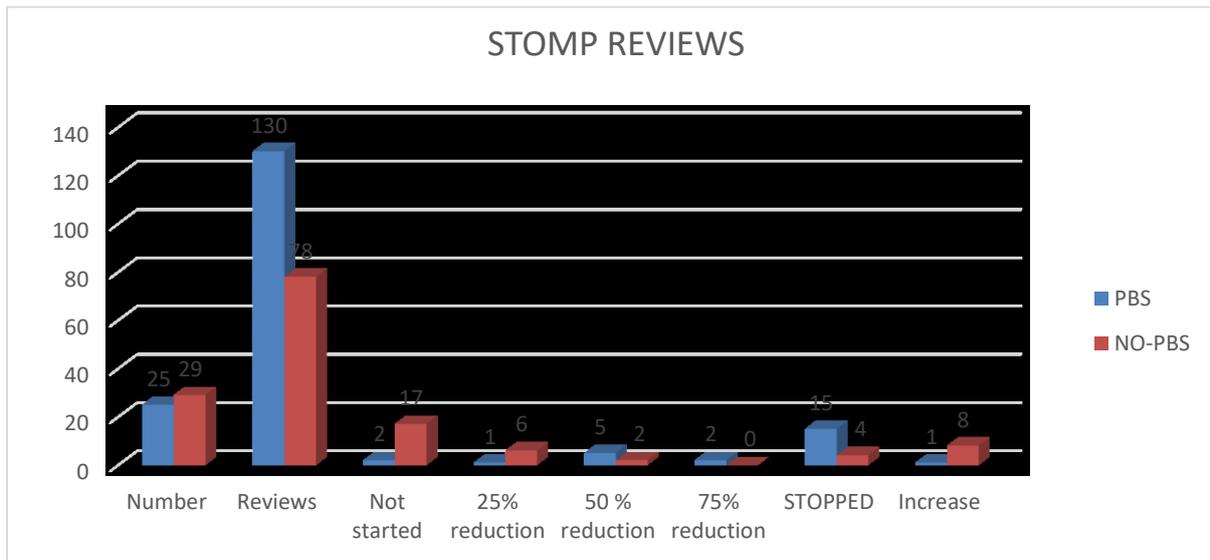


Figure 2. Medications that were challenged by the pharmacist

