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A stakeholder consultation about future research of psychotropic medication use and behaviour support for adults with Intellectual Disabilities who present with behaviours that challenge.

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Abbreviations:

CB-Challenging Behaviour

CBF- Challenging Behaviour Foundation

ID-Intellectual Disabilities

LD- Learning Disabilities

NICE- National Institute of Health and Care Excellence

PH-Public Health

PBS-Positive Behaviour support

PWLDs-People with Learning Disabilities

RCT-Randomised Control Trial

STOMP-LD- Stop over medicating people with Learning Disabilities

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Background

Several recent papers (summarised in Sheehan et al, 2015, 1) and a report by PH England (2) have shown that people with intellectual disabilities (ID) across the lifespan receive high rates of antipsychotic and other psychotropic medications for challenging behaviour despite the absence of an identifiable mental disorder (25% have a record of challenging behaviour vs 21% of mental illness vs 49% receiving psychotropic medication). Our research shows that about 26% who receive prescriptions for antipsychotics have neither a recorded mental illness nor challenging behaviour.

Such prescriptions are usually long term adding to poorer health in the person with intellectual disabilities due, in part, to medication side-effects (Sheehan, Horsfall et al, under review). However, there has been little research in establishing the clinical effectiveness of antipsychotic/psychotropic medication in people with intellectual disabilities and the recent NICE guidelines (3) failed to find sufficient evidence to recommend or otherwise particular psychotropic medications in adults with intellectual disabilities and challenging behaviour. Despite the consensus that clinical trials of psychotropic medication and antipsychotics in particular are urgently needed, the conduct of a trial on this topic is seen as “nearly impossible” due to past failures to recruit participants and the ongoing concerns about condoning overmedication.

However, studies of discontinuation of antipsychotics show (Sheehan & Hassiotis 2017, 4) that many participants whose antipsychotic medication were reduced or discontinued, have had to restart it. It is, therefore, clear that from multiple perspectives, the issue of the effectiveness of antipsychotic medication on challenging behaviour is an important one that urgently needs further evidence.

Aim

The aim of this project was to carry out a wide stakeholder consultation to inform future work in this area. This follows on from the research recommendations made by NICE (2015) which proposed that a randomised control trial to look at the effectiveness of antipsychotic medication and behaviour support for adults with Intellectual Disabilities that present with behaviour that challenges is needed (see appendix 1).

As part of this project, we also aimed to collect data of potential numbers of participants across the London community Intellectual disabilities services. All consultant psychiatrists in London community intellectual disabilities services were contacted to report on numbers of participants with challenging behaviour and on potential eligibility based on a checklist to gauge how many they would be prepared to approach about a future study.

The criteria of individuals we were specifically focused on are as follows:

- A diagnosed intellectual disability (i.e. IQ score <70)
- There has been challenging behaviour* in the last 6 months

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- The individual is 18 years and over
- The individual would consider a change in medication/would be eligible to receive medication
- Currently receiving positive behaviour support** as an intervention

*Challenging Behaviour refers to aggression, destructive behaviour irritability, lethargy social withdrawal, stereotypic behaviour, hyperactivity and inappropriate speech (6).

**Positive Behaviour support refers to behaviour support that includes an ongoing process of assessments and interventions that build on social and other functional competencies to create supportive contexts and preventing occurrence of challenging behaviour (7).

Project Advisory Group (PAG)

This group consists of Professor Angela Hassiotis (AH), Dr Joanna Moncrieff (JM) and Professor Shoumitro Deb (SD). Three teleconferences were set up in the 8 month duration of the project, to discuss progress and findings including direction of future work after the completion of the consultation. There was also information sharing among the PAG via email throughout the project.

Research Team

Production of research materials (i.e. topic guides, accessible information and adverts) were created by research assistant Kate Kimona (KK). Contact with stakeholders and data analysis was carried out by KK and AH.

Method

Data Collection

To initiate the data collection for family carers and service users, 54 community ID services were contacted across London via email or phone to invite them to take part in the consultation. Adverts detailing the purpose of the project and information about the NICE research recommendation were sent to all the services. Due to the nature of this population we gathered data using a combination of convenience and snowballing sampling methods to enhance our reach as much as possible in a limited time frame (8).

Out of these 54 services that were initially contacted, 31 services were carers groups; 18 were service user day centres (including resources hubs providing day opportunities, advocacy and skills based learning) and 6 were a mixture of both. National services for people with ID such as 'MENCAP' and 'The Challenging Behaviour Foundation (CBF)' were also among the services contacted as part of the initial requests for participation in the consultation.

From the first request, 11 services agreed to take part and further discussion was developed about meeting with service users and family carers. From these 11 services, a total of 6

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services progressed to provide the time and the facilities to conduct either group meetings or individual contact details were given for family carers.

Health professionals (mainly psychiatrists working in inpatient and community Intellectual Disabilities ID teams in London) were contacted via email by their academic programme facilitators informing them of the consultation project. The academic programmes take place monthly and are aimed at psychiatrists and allied health professionals for continuing professional development in their work with adults with intellectual disabilities.

Health professionals attended one of the two academic programme study days (North London or South London). The research assistant (KK) attended a session in each programme explaining the rationale behind the consultation. This was followed by a plenary session where professionals' opinions were collected via small group discussions, guided by a broad topic guide based on research and policy concerns and findings or national guidance on good clinical practice. The groups were also asked of their views of the NICE research recommendation.

A further two interviews took place with two experts in the field (Dr David Branford, face to face and Professor Michael Kerr via telephone). Dr Branford is a pharmacist by background and is the pharmacy advisor for mental health and intellectual disabilities as part of the STOMP-LD ('Stop over medicating people with Learning Disabilities') initiative. This initiative looks at reducing the prescriptions of psychotropic medication given to people with Intellectual Disabilities without appropriate clinical indications. Although it is not an evidence based model in this client group, the initiative looks to make changes to the clinical care given to adults with Intellectual Disabilities who require support for challenging behaviour (<https://www.england.nhs.uk/wp-content/uploads/2016/06/stopping-over-medication.pdf>). Professor Michael Kerr is a clinical professor working in the field of intellectual disabilities, epilepsy and psychiatric disorders. He has led a randomised controlled trial for the withdrawal of psychotropic medications in adults with ID and challenging behaviour.

They were contacted via email by AH for their consent to participate in an interview and for their views to be recorded.

Sample

Service users

Two focus groups and one individual interview were conducted; consisting of twelve service users in total (6 males; 6 females). The service users consisted of six individuals whom are currently on a type of psychotropic medication, therefore, provided lived experience. Information was presented in an accessible format for all service users and support by their support workers were also an option for them. Service users consented to have their information presented in an anonymised format for the purpose of this consultation.

Family carers

Four individual interviews were conducted as a response to the adverts sent out to the different services. The individual interviews consisted of four mothers of adults with intellectual disabilities. One carer's service facilitated a focus group for family carers who consisted of eight family carers (6 females; 2 males) with a relative with intellectual

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disabilities and challenging behaviour or knew of someone (i.e. a friend's son or daughter) who had taken psychotropic medication for challenging behaviour. There were a further eight family carers who responded to an email sent out to 40 family carers who were associated with the CBF on behalf of this consultation about their ideas of what future research in this area should consist of.

Clinicians

Two plenary sessions took place across London (North London academic programme & South London academic programme). Altogether 52 health professionals took part in these sessions. Professionals included Consultant Psychiatrists, Specialist Registrars, Clinical Psychologists and Nurses. A total of 21 London based community ID services were represented across both plenary sessions, as reflected in the contact details provided by all participating clinicians.

Wider Perspectives: Expert Interviews

Two interviews were conducted with Dr David Branford and Professor Mike Kerr.

Topic Guides for Interviews and Focus Groups

The topic guides for all the different stakeholders were mainly derived from existing literature around clinical trials and working with adults with intellectual disabilities with challenging behaviour. Topic guides incorporated ethical considerations, risks, motivation, and usefulness of such research and previous experience of support by services.

Research shows that there can be a difficulty in attaining the opinions of people with intellectual disabilities (9). Reasons for this include the presentation of information and the type of demand it places on individuals' capacity to retain knowledge (10). From reviewing papers that explicitly looked to attain opinions of stakeholders in regards to the medication use for challenging behaviour, several factors influenced the style that was chosen for data collection. Hall and Deb (2008, 11) described using open ended questions when speaking with service users as a way to optimise responses. We therefore designed questions that focused on future research and knowledge of medication as oppose to a standardized questionnaire (Arscott et al. 2000) due to this project being a consultation and not formal research.

Easy read topic guides (12) and were posed to the 'The Advocacy Project' for people with ID, based in Camden. They were consulted on about the style of questions, relevance of pictures and the readability of the format. The feedback from this group led to the topic guide being revised prior to being used. Literature shows that it can be difficult for people with intellectual disabilities to answer particular questions about medication (11). Heslop et al. 2005, (13) also found that service users knew little about what medication actually does. Such studies influenced the topic guide to explore what knowledge service users retained about the psychotropic medication they have been prescribed. Service users were also asked if they would consent to participate in future research that involved medication changes; thus relating to the NICE research recommendation of a potential randomised controlled trial.

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The topic guide for family carers was created based on literature which specifically sought the views of family carers and support workers about medication. Research from Hall and Deb (2008, 11) as well as Donley et al (2011, 14) reported family carers and support workers lacked information about medication given to relatives or people they cared for with ID. The semi-structured interviews explored the reasons why people with ID are given medication, which health professionals prescribed this medication and whether the medication was effective. In the focus group setting, the same questions were asked however with fewer prompts from the facilitator (KK) due to participants having more 'ownership' in this type of data collection (15).

Clinicians were given eight questions to discuss among their small groups pertaining to their views on the NICE research recommendation, their willingness to support future research, their concerns in regards to risks and ethical considerations of such research and their thoughts about the implications future research can have on clinical practice.

Data Analysis

All individual interviews and focus groups were audiotaped and transcribed verbatim. The analysis was guided by the framework approach. As such, the analytic process is deductive in that it is guided by the aims of the study, but is simultaneously inductive and flexible and therefore allows key themes to emerge. A combination of context and thematic analysis formed a base pulling out a lot of the emergent themes from the transcripts. These approaches were preferred as data was analysed from semi-structured interviews as well as focus groups. For themes to be drawn from the data, re-reading of the transcripts several times was part of the process. Content analysis is described as mechanical as well as interpretative (16). It involves physically organising and subdividing the data into categories, as well determining what categories are meaningful in regards to our research questions. Thematic analysis was drawn upon in terms of the interpretive component. The themes were organised and structured using the qualitative analysis software NVivo.

Results

Service Users consultation

Service users were asked a series of short questions related to what medication they were currently taking; any knowledge about the purpose of their medication as well as their thoughts in taking part in future research. The results described below are the incorporated answers of the six service users who were currently on a psychotropic medication for their behaviour. From the two focus groups conducted and one individual interview carried out, the data collected was grouped within four main themes:

1. What is the medication and its purpose

Three of the six service users that were currently on a type of psychotropic medication were able to name the medication they are prescribed. Four of the six service users currently on medication could explain what the medication was also used for. Only one of

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the six service users was able to broadly explain the purpose of their combination of medication. The example below illustrates some responses to the questions:

Question 1: Do you know what medication you take?

“Sodium Valproate, Amitriptyline, Diazepam, Lorazepam” (service user 1)

Question 2: Do you know why you take your medication?

“I take medication to keep calm” (service user 1)

“It’s for anxiety and mood swings” (service user 3)

The responses, although show some detail are very simplistic and could be an indication of how much service users retain information or how much information they have been given by carers or clinicians.

2. Accessible information

In terms of accessible information, five out of the six service users were able to report that they received information from a nurse, pharmacist or doctor. Only one individual was unable to answer this question. Responses were fairly short and therefore it was unknown if service users had support in receiving this information (i.e. parents, support workers). A brief answer is illustrated below:

“I get told by the pharmacist” (service user 2)

There was no indication of whether accessible hand-outs have been given to individuals. This illustrates that further understanding of how service users are given information about their medication should be explored.

3. The importance of Medication

All six service users reported that they found medication important; however answers varied in terms how important they found medication in comparison to other needs such as housing and support services.

“It’s not as important as other things” (service user 2)

From such answers, it is important to consider how much impact a service user may feel their medication may have on their daily life in comparison to what else they may feel is important to them.

4. Interest in future research

Service users were asked if they would be comfortable taking part in a potential future trial, which may involve changing their current medication. Two of the six service users did not want to take part in anything that involved a medication change, answers included:

“I would not want to get ill again” (Service user 3)

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From such comments, consideration should be towards how service users would be made to feel safe in the context of a future trial. Addressing fear that service users may have would aid recruitment as well as retention in a future study. It is also important for researchers to specifically state that an RCT may not necessarily lead to a change in medication that could potentially lead a participant to become ill; rather for them to start new treatment, which could aid their wellbeing.

Family Carers

Content and thematic analysis were used to show the rich detail family carers gave in regards to their views on the NICE research recommendation and the current care which the relatives they care for are experiencing.

Theme 1: What variables have an effect on behaviour?

Family carers involved in this consultation, expressed in various ways about their views on the variables that could contribute to the different displays of behaviours that challenge. The four main subthemes out of this topic are listed as:

- Environmental effects
- Communication difficulties
- Underlying mental health diagnoses and other complex needs
- Management of other physical conditions

Some family carers expressed their view that it is more about the environment in which their relatives were in that affected the behaviour they displayed. Such statements as mentioned below, explain this:

“He was going through a lot of personal problems, my husband at the time, his father and I split up, there was another baby born into the family. He went to boarding school so a lot of what was happening was not looked into...” (Family Carer 1)

The acknowledgement of wider systemic issues was discussed by three of the four individual interviews, which indicates, a factor that should also be considered when looking at potential confounding variables with any future studies. Family carers told us that explanations for behaviours were being overlooked when it came to prescribing medication. Furthermore, two of the family carers expressed the communication difficulties that their relatives had and how showing challenging behaviours is a way to communicate needs. The example below describes this:

“I have had years of experience with him, so I realized they were hallucinations he was having. It’s really unfair as he can’t communicate. Can you imagine? You know you usually get people who are hallucinating shout out things like that, he can only give it through physical behaviour” (Family Carer 3).

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Theme 2: What do family carers want?

Views were expressed very clearly about what family carers would like from services and the way their relatives are cared for. There was a particular emphasis on the involvement of carers in decision making of support provided for their relatives. This is an important factor to look at in terms of future research as it could impact the level of engagement by family carers to monitor changes due to medication changes. The main subthemes are listed below:

- Listening to family carers opinions and their involvement in decision making
- Support for family carers
- Knowledge Family carers have about medication

A particular quote that emphasises the position of family carers is displayed below:

“I think as a carer I do feel vulnerable because this is about my son with disabilities and he is not able to make choices, that mean I have to make their choice, or the professional makes their choice.” (Family Carer 2).

All four of the individual interviews as well as the focus group expressed their lack of knowledge about medication being given to their relatives and a few carers further expressed they did not know what antipsychotics were. It was apparent that information gained was not necessarily from health professionals. Here is an example of a family carer explaining how she learnt about her son’s medication.

“I had to research, I did take the name of the medication and I had to research and then I went to ‘MENCAP’ which we had a parents group and there I got a lot of information there” (Family Carer 1).

Theme 3: Does Medication work?

Looking specifically at the effectiveness of medication, four particular subthemes came from the interviews and focus group. These are detailed below:

- The difficulty with working with people with limited or no verbal communication
- Lack of understanding about the dosage prescribed and the length of time medication is used for
- Worry about side effects of medication
- Did medication alleviate the behaviour?

A common theme that was constantly spoken of was the side effects of medication and whether this outweighed the benefits of the challenging behaviour observed. Three out of the four family carers who had individual interviews expressed that the medication prescribed to their relatives did not alleviate the targeted behaviour. Two of the carers from the individual interviews, expressed that the medication had helped with the behaviour that

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was of concern to them. The example below details an area of concern regarding side effects:

“If I had a choice now I think parents and carers need to be given a choice...what’s happened with my son is that he has had it in his childhood but carried on into his adulthood and I am at that stage where he would develop almost breasts from it.”(Family Carer 3)

This family carer expresses her concerns about side effects and also states the length of time her son has been on medication. A new study should consider how they will address concerns about side effects and also clear explanation to parents about what medications are being tested.

Theme 4: The Support System

The emphasis within this theme was how family carers perceived the health and social support they have received. What is highlighted especially in this theme is their perception of how support was given and the challenges family carers felt they had when working alongside health professionals to obtain the best care possible for their relatives. Here are the main sub-themes that consistently emerged from the data.

- Inexperienced support staff
- How do clinicians decide when to prescribe medication?
- Increased choice of alternative treatment options as oppose to medication
- Difficulties with withdrawal
- Lack of availability of specialist assessments for behavioural difficulties

Within the various discussions with family carers, it was often mentioned if alternative approaches could be offered rather than medication as a first instance, or even as a second option, if medication was appearing to fail in alleviating the challenging behaviour.

“...why does the doctor offer you that? [Medication]...what about that specialist assessment? Surely in the long term this is more helpful then giving my son tablets.” (Family Carer 3, Focus group).

It was also felt that the decision making for medication was influenced more by the health professionals as oppose to the family carers, and some family carers expressed feelings of helplessness in bringing their views across when it came to deciding if medication was the right path of treatment.

“I think they just need to watch what they give the child basically...because the hospital can take over the decision. It’s like, you feel like you as a parent you have done something wrong. You feel the pressure.” (Family Carer 4).

Theme 5: Future research

In regards to future research and support for a proposed new study, the family carers showed a lot of interest. Out of the 12 family carers who were specifically asked about their

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support for future research, six family carers agreed this was a priority for research proposed by the NICE guidelines. Only three family carers reported they would support their relative being part of a future study. This was because, they didn't think it would be appropriate for their child to be part of such a study. Others felt that medication was not the answer to solve issues, or they were concerned about the risks that could arise in changing the current regime for treatment. Below are the main subthemes that emerged:

- Alternative treatment options
- Side effects of medication
- Do they support NICE guidelines?

Here is a quote by a family carer who had strong views about alternative treatments being the focus of future research as oppose to looking at the effectiveness of medication.

"We shouldn't be focusing on medication. I think we should be focusing on holistic therapy and maybe introducing it, obviously now they are all adults but introducing it in part of the psychology intervention that they receive, rather than focusing it more on medication."
(Family Carer 3)

The family carers linked to the CBF (n=8) who were contacted via email, reported similar views to those seen face to face. Therefore no new subthemes emerged from their responses. Quotes below reflect their opinions of what else research should look into:

"I would like research to be carried out to try to find the optimum dose of antipsychotic medication which relieves the anxiety and challenging behaviour, but does not overly sedate the person."(Email respondent 1).

"How does epilepsy affect prescribing and use of antipsychotics? In my experience the possibility of increased seizure activity was considered an acceptable side effect. How can unwanted effects be measured in those who are nonverbal and cannot localise pain or indicate other discomfort?" (Email respondent 2).

Health Professionals

Within the two plenary sessions that took place, specific questions were asked about their view of prioritising the NICE research recommendations, if they would be in support of future research and their concerns in regards to clinical risks and ethical considerations for any future studies. It was not possible to use content analysis for this part of the data, as the health professionals worked in groups to answer the questions, and therefore there was a limitation in that not individual opinions of all clinicians were collected. Details of the main themes emerging are provided below.

Theme 1: Limited knowledge available about psychotropic medication

Health professionals expressed their dissatisfaction of the current state of knowledge available to clinicians and families. The subthemes that emerged in this discussion are as follows:

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- Clinicians tend to base views about clinical trials on one failed study
- Limited resources (e.g. accessible leaflets) to give family carers and service users about medication

The general consensus was that there should be more information about psychotropic medication available to inform their clinical decisions in managing challenging behaviour as well as providing information to family carers. Such comments were made by clinicians in regards to access to information and knowledge are illustrated below:

“I have discussions with clients about medication but don’t have access to accessible information/leaflets to give clients”

“Evidence base in LD and challenging behaviour is poor/patchy”

“Limited evidence for challenging behaviour with no MH diagnoses/ conflicts with anecdotal knowledge”

Theme 2: Methodological and ethical issues

Clinicians expressed various opinions about what needs to be prioritised in terms of methodology and also the importance about being explicit with defining terms, such as the definition of “challenging behaviour” within intellectual disabilities. The subthemes that occurred are as follows:

- Clarity about what the defined outcomes and outcome measures
- The challenges in including non-verbal participants
- Account of other confounders that may impact behaviour
- Capacity and consent issues
- What are the specified risks of harm to self and others due to potential medication change?

Some of the answers gathered from the discussion showed the variability in how clinicians thought of the methodology in carrying out future research, particularly with this client group. Some quotes are illustrated below:

“There is difficulty in ruling out mental health illness in non-verbal/severe LD patients with challenging behaviour”

“Outcome measures: how to identify change”

“Many of our patients are prescribed antipsychotics as best interest decision”

“Hard to get RCT ethics approval for randomisation”

Theme 3: Clinician understanding of the different research designs

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Clinicians were asked about their opinion on the research recommendation from NICE. The focus of the opinions was the merit of randomised controlled trials and of other designs. Therefore the subtheme in this section is as follows:

-RCTs vs. other designs (e.g. cohort studies)

Some clinicians felt an RCT would not be appropriate for this group. This would be an important factor to consider when designing a new study as it appears that the type of research design would influence a clinician's decision to support the study and refer participants. This is illustrated by the responses below:

"Is case control methodology a better way forward than RCTs?"

"Could a cohort or retrospective study be a pre cursor?"

"Would an RCT be appropriate?"

Theme 4: What would a pathway look like for future study?

Clinicians were also concerned about who retains clinical responsibility during a trial and other trial specific procedures, e.g. end of trial, introduction of trial medication. There were a range of answers from both plenary sessions about what conditions would need to be in place for participants to be referred. This included having contingency plans, clinical responsibility for risks and 'right to withdrawal' procedures. Discussions included the following quotes:

"Need an established protocol/pathway for patients who deteriorate or become more challenging during the trial...how will treatment therefore change?"

"Who will be the responsible clinician or consultant for the patient?"

"That the intervention could be 'reversed' if patients on the trial get worse"

"Would need to know what services could do if patients in the trial were to deteriorate (i.e. back up)"

Theme 5: Research set up

Significant discussion took place about how services might be motivated to engage with a clinical trial. This highlighted important indications for future research and diverse responses emerged. Here are the main subthemes:

-Education about research to services prior to starting

-What will be the length of time the research would be proposed for?

-Who will hold the overall clinical responsibility for a participant involved in a potential trial?

-Funding implications for services/carers (e.g. extra staff for services, monetary incentives for families)

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The research set up was a very important point and led to many clinicians asking a lot of questions about the practicalities of this research to take place. The quotes below show some of the discussions:

“Would there be support [extra resources to help carry out research] for clinical teams?”

“More services required to support changes and medication”

“Positive financial incentive for the service might be something to consider

“Services would only agree if extra resources [e.g. Extra staff] would be made available if needed- excess treatments costs covered”

Theme 6: What other research questions could be investigated?

Lastly, we asked clinicians what other research questions do they believe could be looked at in this area. What is highlighted within this question is that a lot of the clinicians were keen in keeping research very specific to medication as oppose to exploring alternative treatments for managing challenging behaviours. This shows a clear contrast to what family carers have specified. Moreover, there is a clear interest for research in medication to be developed further. Responses included:

“Which medication is most effective for challenging behaviour?”

“What does efficacy look like?”

“Do antipsychotics work for CB? - Should try and know this before we look at whether it works with a psychosocial intervention”

“Qualitative research into the experiences of PWLDs starting on psychotropic medication (looking at choice and side effects)”

Wider context: Expert Interviews

Dr David Branford and Professor Mike Kerr were both interviewed to draw on their views about a future study as detailed by the NICE guidelines. Both interviews drew upon their positions within the field and their own expertise.

Interview with Professor Mike Kerr:

The main themes that came from this interview included: views about the current priority for medication research; safety procedures for future trials; use of challenging behaviour tools in future studies; Risk involved in taking away medication and other research questions to consider. From the interview, Professor Kerr expressed his opinion that the priority should be to investigate withdrawal of medication in adults with intellectual disabilities. He also said that the safety procedures for any service users involved would be his biggest interest in any future work that was to take place.

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“Well I think that safety would be my first point. I would like to see the safety”

“I think there is still an issue about coming off medication. I think the next level is to do a trial supporting coming off medication “(Professor Mike Kerr, Interview with Kate Kimona, February 2017).

Professor Kerr considered that an observational study design looking at participants who need to undergo a medication change would be an important starting point for future research, rather than trialling a new RCT looking at the effectiveness of two different medications.

Interview with Dr David Branford:

The main themes that were drawn from the interview with Dr Branford included: The problem with recruiting from this population, the length of time individuals have been prescribed antipsychotic medications, the benefits of involving other services into future work and the influence of the ‘Transforming Care’ and “STOMP-LD” project. The main points that Dr Branford highlighted were the lack of literature for adults as well as other government initiatives. These quotes illustrated some of his opinions:

“There is such a divergence in that children’s literature and the adult’s literature, and the adults literature is so dominated by the failed study that it is really difficult to know what to do because that study failed to recruit”

When asked specifically about his opinion of designing a new RCT, Dr Branford, was in agreement for a new trial to take place, however he expressed his concern about recruitment being a problem. He gave his idea of how a new trial should be set up, which is detailed below:

“...there has never been a better time to do a decent trial where you get a large number of people, you train them up in positive behaviour support, you try then to remove their drugs using positive behaviour support and see what happens.”

When asked about his support for future research and if it can take place with other national initiatives, Dr Branford said this:

“So we have got it on many fronts, firstly its priority this government seems to continue the previous governments desire to keep this a priority, it’s one of the first four NHS England priorities. Politicians are very engaged and there is a lot of money, people are throwing a lot of money at it at the moment. And actually when you look at it, the country spends a lot of money in this area you know it’s a hugely big area isn’t it. So all those things make it like yeah now is the moment really” (Dr David Branford, Interview with Kate Kimona, February 2017).

In conclusion of these interviews, the feedback was positive about some type of research to be conducted within this area of antipsychotic use in adults with intellectual disabilities.

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Opinions differed in terms of what type of research focus should be prioritised in relation to research recommendations from NICE.

Discussion

Implications

From all the data gathered about stakeholder's opinions, there were some key implications to be considered for future research. In regards to service users, future research should take into account what potential participants' current knowledge is of their prescribed medications. This may have implications for informed consent to take part in future research. Discussions with service users should also involve researchers to understand what service users know about the benefit or difficulties they currently have with medication and what their concerns would be if they were to take part in a potential trial (e.g. fears around medication changes). Information that is accessible and is understood by carers as well would be a benefit to promote clear understanding of what future research would entail and help service users to stay engaged. Although the sample was small for this project, there was a clear indication that there are perceived information gaps about psychotropic medication especially for people with ID; this suggests greater knowledge gaps in those potential participants who are unable to communicate their understanding of medication. A carefully formulated way of developing resources for a future study needs to be considered.

Information collected from family carers, highlighted a few main issues which would need to be considered in designing a potential future trial. Firstly, the role of family carers in providing support to relatives would need to be established at the beginning of a project. From the opinions collected, the general consensus was that family carers did not feel in control of decisions being made and felt it was not their place to make the final decision about their relatives starting medication because of their lack of medical knowledge in comparison to clinicians. The family carer respondents were also keen on considering alternative approaches to medication. This varied across family carers as to who were offered alternative treatments by clinicians. From the majority of the interviews and the focus group discussions, family carers did tend to deviate from the topic of medication and did at times discuss other related issues for their carers (i.e. housing support, support in day services). As this NICE research recommendation seeks to see how specifically antipsychotics work alongside behaviour support, it would be important for researchers to be explicit to family carers in future research relating to this recommendation that looking at the medication use of adults with ID take would be central to investigating effectiveness of treatment for challenging behaviour.

Clinicians shared very diverse views on the implications of carrying out future research involving their health teams. Opinions such as clear explanations to be given to other allied health professionals of their role in the research, the need for extra resources and incentives for teams were all common themes. The results showed an overall support from clinicians for future research however opinions varied in terms of the type of research design that should be used with this clinical group. Many clinicians raised questions about the research design and about the practicalities of a large scale research study could occur. The view of

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whether an RCT was the best way to conduct new research, did vary and the support overall was not very strong. Such queries indicate the need for training in how research is carried out in health services to be offered before any new study can be begin. Consideration for any research should include the current limited resources that health services for Intellectual disabilities are facing. How research can take place involving clinicians who may already have dual roles (i.e. case management as well as clinical roles) can also impact the data collection.

The feedback from the expert interviews further illustrated the need for future research to take place, however what the focus should be differed. From the interview with Professor Kerr, it was clear he saw the importance of more research to be carried in this client group due to current ongoing issues they are facing (e.g. problems with withdrawal from medication). His focus on safety of service users involved in future research is an important element to consider when designing a future study. Dr Branford also showed strong support for future research, specifically an RCT and indicated that alongside the 'STOMP-LD' initiative, there is room for more research examining the effectiveness of psychotropic medication and specifically how long medication should be prescribed for.

Limitations of the study

From this stakeholder consultation, there are a few limitations to take note of which has impact on the conclusions that can be drawn from this study. Firstly, the data collected only considered the opinions of the clinicians, family carers and service users. Opinions from support workers were not collected in this study, which can be seen as a limitation as they have their own experiences of how psychotropic medication have impacted the adults with ID and challenging behaviour they care for. A number of studies have looked into the opinions of support workers in regards to medication and some interesting points have been raised. For example, in a qualitative study looking at support worker's opinions (Lalor and Poulson 2013, 17), it was reported that support workers very sensitive in noticing the changes and experiences of their clients on psychotropic medications. Support workers were able to explain how clients were affected by medication and perceived themselves as genuine experts on their clients and their lack of training is a weakness in the care of people with intellectual disabilities. A number of authors have highlighted the influence that care staff have on the decision of prescribing or not prescribing medication for people with intellectual disabilities (see review by Deb, 2016, page: 362, 18).

Another limitation to note is the study was limited to a metropolitan urban area of England. Data did not anticipate differences from other services across the UK and therefore the data collected is not representative in this way. Furthermore actual data collection was also a big obstacle through this process, as participation from service users and family carers were low. As shown by other studies (9, 11) data can be difficult to obtain from this population group and therefore the results should be looked at with caution as this is not representative of all stakeholders in the UK. A factor in the small sample size is also due to the time allocated to collect the data therefore could have limited responses included in this report.

Due the nature of this study being a qualitative piece, the biases of the researchers could have had an impact on the data collection process (e.g. what prompts were given during interviews and why) as well as data analysis. The method of using focus groups as a part of

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data collection can be limiting in understanding individual thoughts, feelings and experiences due to contrived speech being produced as a result of artificially formed groups for the researcher's purpose (19).

As part of the project protocol, we originally set out to collect potential numbers of the participants that fit the criteria from consultant psychiatrists based in community intellectual disabilities teams in London. However it quickly became apparent that collecting the data was a difficult task due to low rate of responses from clinicians and lack of a register that could identify that information. On reflection, we propose that looking at average figures across the country would be a better indicator for making recruitment assumptions for a future study.

Conclusion

This feasibility study set out to look at the stakeholder opinions specifically in regards to the NICE research recommendation (2015) on an RCT of antipsychotic medication and positive behaviour support for adults with ID and challenging behaviour. Qualitative data collection and analysis were incorporated to gather as much information as possible from various stakeholders. Stakeholders show a clear interest in further research taking place, with the majority agreeing with the research recommendations from NICE; however there is not a strong support for future research to be a randomized control trial.

What is important to note about developing a new research study in this area, is the issues raised from service users in regards to fear of medication changes and giving them as much information as possible for an informed decision to consent. For family carers, the concerns around involvement in decision making of their relatives care can impact their decision to support their relative becoming a participant in a potential trial. It would be important for future researchers to consider how best to engage and empower family carers to be involved in research and reassure them in supporting new research. From the view point of health professionals, especially consultant psychiatrists who would have clinical responsibility of any potential participants, addressing concerns around support for the service and clear research protocols to manage risk, will likely increase participation.

During the course of this stakeholder consultation the importance of public and patient involvement in preparing for a future research project was highlighted in different ways. The involvement of 'The Challenging Behaviour Foundation (CBF)' and the links to 'STOMP-LD' have impacted the data we received in given a broader view and realistic context of how new research in this field will be seen by those involved. Data from a group of family carers associated with CBF allowed this project to reach a wider but more specific audience. Further talks about the 'STOMP-LD' initiative with Dr Branford, also gave an understanding in that any further research would be supported which look at ways to reduce or withdraw individuals from long terms uses of psychotropic medication for challenging behaviour. Although the consultations described in this report were from practitioners, service users and families from and around London, we argue that the concerns expressed are more general and shared across similar stakeholder groups in other services in the UK. The findings

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indicate potential avenues to start developing a new research study that could satisfy the recommendations highlighted by NICE.

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Appendix 1: NICE (2015) Research Recommendations

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NICE Research recommendation (11):

Are interventions based on the science and practice of applied behaviour analysis or antipsychotic medication, or a combination of these, effective in reducing the frequency and severity of behaviour that challenges shown by adults with a learning disability?

It is reported in the guideline that little is known about which people respond best to which interventions (e.g. positive behaviour or medication) or about the duration of the interventions.

NICE recommends that the above question should be addressed by a programme of research evaluating these interventions that includes:

“Assessing the feasibility of the formal evaluation of the interventions in a randomised controlled trial (in particular, recruitment).”

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