



STUDY PROTOCOL

REVISED

Management of psychotropic medications in adults with intellectual disability: a scoping review protocol [version 2; peer review: 1 approved, 2 approved with reservations]

Ashley Costello ^{1*}, Cian Hehir ^{1*}, Drona Sharma², Eithne Hudson¹, Owen Doody ^{3,4}, Dervla Kelly ^{1,3}

¹School of Medicine, University of Limerick, Castletroy, Limerick, Ireland

²Nua Healthcare Services, Republic of Ireland, Ireland

³Health Research Institute, University of Limerick, Limerick, Ireland

⁴Department of Nursing and Midwifery, University of Limerick, Castletroy, Limerick, Ireland

* Equal contributors

V2 First published: 22 Mar 2021, 4:30
<https://doi.org/10.12688/hrbopenres.13170.1>

Latest published: 12 Jan 2022, 4:30
<https://doi.org/10.12688/hrbopenres.13170.2>

Abstract

Introduction: Psychotropic medications are commonly prescribed among adults with intellectual disability (ID), often in the absence of a psychiatric diagnosis. As such, there is great disparity between the estimated prevalence of mental illness and the rates of psychotropic medication use amongst people with ID. 'Off-label' use of these medications may account for much of this discrepancy, in particular their use in the management of challenging behaviour. This has come under scrutiny due to the myriad of side effects and the deficiency of high-quality data supporting their use for this indication.

Understanding the causes and justifications for such disparity is essential in discerning the efficacy of current prescription practice.

Objective: To explore the existing evidence base regarding the prescription and management of psychotropic medications in adults with ID. The aim will be achieved through identifying the psychotropic medications commonly prescribed, the underlying rationale(s) for their prescription and the evidence available that demonstrates their appropriateness and effectiveness. Additionally, the paper will seek to evaluate the availability of any existing guidance that informs the management of these medications, and the evidence and outcomes of psychotropic medication dose reduction and/or cessation interventions.

Inclusion criteria: This review will consider studies that focus on the use of psychotropic medications amongst patients with ID.

Methods: Research studies (qualitative, quantitative and mixed design) and Grey Literature (English) will be included. The search will be conducted without time restrictions. Databases will include: Ovid

Open Peer Review

Reviewer Status ? ✓ ?

Invited Reviewers

1 2 3

version 2

(revision)
12 Jan 2022

version 1

22 Mar 2021

? report ✓ report ? report

1. **Lotte Ramerman** , Netherlands Institute for Health Services Research, Utrecht, The Netherlands
2. **Ashok Roy** , Coventry and Warwickshire Partnership NHS Trust, Coventry, UK
University of Warwick, Coventry, UK
Health Education England, London, UK
3. **David Harley** , The University of Queensland, Herston, Australia

Any reports and responses or comments on the article can be found at the end of the article.

MEDLINE, Embase, CINAHL, JBI Evidence Synthesis, Cochrane Central Register of Controlled Trials, Cochrane Databased of Systematic Reviews, PsycINFO and Scopus. A three-step search strategy will be followed, with results screened by two independent reviewers. Data will be extracted independently by two reviewers using a data extraction tool with results mapped and presented using a narrative form supported by tables and diagrams.

Keywords

Intellectual Disability, Prescribing, De-prescribing, Psychotropic Medicine, Medication, Medication management, Scoping Review

Corresponding author: Dervla Kelly (dervla.m.kelly@ul.ie)

Author roles: **Costello A:** Conceptualization, Methodology, Project Administration, Writing – Original Draft Preparation; **Hehir C:** Conceptualization, Methodology, Project Administration, Writing – Original Draft Preparation; **Sharma D:** Conceptualization, Methodology, Supervision, Writing – Review & Editing; **Hudson E:** Writing – Review & Editing; **Doody O:** Conceptualization, Methodology, Supervision, Writing – Review & Editing; **Kelly D:** Conceptualization, Funding Acquisition, Methodology, Supervision, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

Grant information: Health Research Board [ECSA-PA-2020-014]. This work was supported by the Health Research Institute, University of Limerick.

Copyright: © 2022 Costello A *et al.* This is an open access article distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

How to cite this article: Costello A, Hehir C, Sharma D *et al.* **Management of psychotropic medications in adults with intellectual disability: a scoping review protocol [version 2; peer review: 1 approved, 2 approved with reservations]** HRB Open Research 2022, 4:30 <https://doi.org/10.12688/hrbopenres.13170.2>

First published: 22 Mar 2021, 4:30 <https://doi.org/10.12688/hrbopenres.13170.1>

REVISED Amendments from Version 1

Our updated manuscript reflects suggestions and recommendations from the peer review process.

- We have deleted any unnecessary abbreviations to promote readability.
- We have amended our use of 'ID population' to 'population with ID' through our manuscript.
- As recommended by one of our reviewers we have amended our definition of challenging behaviour to a broader, more descriptive definition as defined by the Royal College of psychiatrists.
- We have amended and updated references as per reviewer suggestions and have acknowledged previous similar research.
- In our Methods section we have updated inclusion criteria: English language only as decided during our search process.
- We added 'case studies' in our exclusion criteria.
- We also explained the development of our data extraction tool.
- Other minor edits were made to improve readability.

Any further responses from the reviewers can be found at the end of the article

Disclaimer

The views expressed in this article are those of the author(s). Publication in HRB Open Research does not imply endorsement by the Health Research Board of Ireland.

Introduction

Intellectual disability (ID) is defined as a lifelong disorder that includes both intellectual and adaptive functioning deficits in conceptual, social, and practical domains, the onset of which occurs during the developmental period of life¹. The global prevalence of ID is estimated to be approximately 1%^{2,3}. The reported prevalence of mental illness amongst adults with ID is inconsistent; one systematic review reported prevalence figures ranging from 3.9 to 46.3% whilst others report an even broader range that spanned from 13.9 to 75.2%^{4,5}. It has been identified that people with ID are faced with challenges in gaining access to psychiatric healthcare and support which may pose as an obstacle to formal diagnoses^{6,7}. The presence of Diagnostic Masking and Diagnostic Overshadowing have been identified as potential barriers to formal clinical diagnoses within this cohort; Diagnostic Masking describes a clinical scenario when symptoms of mental illness are concealed or masked by pre-existing ID while Diagnostic Overshadowing occurs when clinicians circumscribe the diagnostic process and mislabel complex symptoms of mental illness as manifestations of ID⁸. Further to these barriers, atypical clinical presentations of psychiatric illness, along with communication and health literacy barriers may contribute to an overall underestimation of prevalence of mental illness in the population with ID^{3,9}. Despite the disparity in reported prevalence,

coexisting mental illness is suggested to be more prevalent in people with ID compared to the general population^{4,5,10}

For the purpose of this scoping review, the four major classes of psychotropics we will focus on are antipsychotics, antidepressants, anxiolytics and mood-stabilisers, which include lithium and anti-epileptics with mood stabilising indications. Although many of these medications indeed have indications for the management of mental illness, research has indicated poor correlation between the prescription rates of these medications and the rates of diagnosed mental illness in the population with ID^{11,12}. This discrepancy has been attributed to the 'off-label' use of psychotropic medication for the management of challenging behaviour, which is an unauthorised indication. As defined by The Royal College of Psychiatrists, challenging behaviour is behaviour of such an intensity, frequency or duration as to threaten the quality of life and/or the physical safety of the individual or others and is likely to lead to responses that are restrictive, aversive or result in exclusion¹³. It may include behaviours of a destructive nature, such as aggression, violence and self-injury^{14,15}. Challenging behaviour can also be an attempt to communicate unmet needs which require identification of causes and promotion of positive behaviours and addressing social needs¹⁶. It is recognised that people with ID are at a higher risk of exhibiting challenging behaviour; the prevalence of which is typically quoted between 10 and 15%^{14,17}. According to the National Institute for Health & Care Excellence (NICE) guidance, rates of challenging behaviour are higher in the early 20's age group and can be as high as 30–40% in hospital settings¹⁸. As a consequence, the patient cohort with ID are at increased risk for prescription of psychotropic medications not only for the management of mental illness, but also for the treatment of challenging behaviour. Research carried out in the United Kingdom (UK) and North America has suggested that challenging behaviour is one of the most common reasons for the prescription of psychotropic drugs¹⁹. Despite their widespread usage, there exists a dearth of high quality data available to inform the provision of these medications in this patient subgroup^{20,21}.

Concerns regarding the prescription of these medications to people with ID have been raised over the years³. Psychotropic medications are associated with a myriad of risks ranging from metabolic and hormonal dysfunction to extrapyramidal side effects that can adversely affect movement. They are also associated with cardiovascular side effects such as arrhythmias and QT-interval prolongation, hyperglycaemia and weight gain, along with the risk of potentially fatal neuroleptic malignant syndrome^{22–24}. Such a combination of side effects becomes increasingly concerning considering a higher prevalence of significant comorbidities, lessened seizure thresholds and a reduced capacity to self-report adverse effects within this highly vulnerable patient group²⁵.

NICE advises implementation of psychological and environmental interventions for the management of challenging behaviour as the first step and recommends the consideration of

psychotropic medication only in particular circumstances; for example, when there is a severe risk to the person or others¹⁸. These guidelines recommend the continuation of these medication on the basis of a beneficial response. With this in mind, it would seem that to achieve reduction and/or cessation of these medications would be a desirable outcome. Despite this, people with ID tend to be treated at high doses of psychotropic medications and for prolonged periods of time⁹. What is more, the challenging behaviour for which psychotropics are frequently prescribed to manage often remains unchanged^{26,27}.

The aim of this scoping review is to investigate the literature available on the use of psychotropic medications within the ID cohort to manage challenging behaviour. While similar reviews have been carried out in the past, this review aims to provide an up to date review of the literature^{28,29}. In particular, this review aims to identify what psychotropic medications are prescribed to adults with ID, why they are prescribed to this patient cohort and how these medications are managed over the long term. This will be carried out by including interventions that aim to achieve dose reduction or complete cessation of psychotropics and to identify the associated risks and benefits that accompany this reduction/cessation. As we are also interested in dose reductions of psychotropic medications and any accompanying psychological or social educational intervention components for challenging behaviours, we choose to undertake a scoping review rather than a systematic review to include de-prescribing studies and heterogeneous study methodologies. This scoping review will assist to identify any gaps in the literature available and to help guide and recommend future studies and systematic literature reviews within this area of research.

Research questions (RQs)

- 1) What psychotropic medications are commonly prescribed among adults with ID?
- 2) What is the clinical indication(s) for prescription of such medications?
- 3) What evidence base (if any) exists to support the prescription of psychotropic medications, including 'off-label' use in adults with ID?
- 4) What guidelines/policies exist regarding the management of psychotropic medicines once they are prescribed among people with ID?
- 5) What interventions (if any) are available to facilitate dose reduction or cessation of psychotropic medications among people with ID?
 - How have such interventions been evaluated to date? i.e. what outcomes are measured?
 - What are the potential benefits and risks associated with the reduction or cessation of psychotropic medication?

Methods

The protocol was drafted according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for Scoping Reviews (PRISMA-ScR) protocol³⁰.

Inclusion and exclusion criteria

Inclusion criteria

- Participants: all adults (>18 years of age) with ID, regardless of demographic or clinical characteristics.
- Concept: interventions and/or phenomena of interest (reduction/cessation of psychotropic medications in adults with ID).
- Outcomes:
 - Any qualitative or quantitative outcome reporting on psychotropic medication use and behaviours among the population with ID.
 - Any qualitative or quantitative outcome reporting on psychotropic medication safety measures (adverse drug event, adverse drug reaction, medication error, adherence, compliance, consumption, drug-related problems).
 - Any professional practices by healthcare providers in relation to managing psychotropics in the population with ID.
- Study design: all research designs including reviews (systematic, integrative and narrative) and research (qualitative, quantitative and mixed design studies). In addition, national and international policies, strategies, guidelines and standards will also be examined.
- Year of publication: No restriction.
- Language: English language only.

Considering the small body of research available on this topic, broad inclusion criteria were developed to ensure all relevant research is captured whilst reducing the risk of omissions.

Exclusion criteria

- Article types: commentaries, editorials, opinion pieces, non-systematic literature reviews, case studies.
- Clinical trials of medicinal products.

Search

The proposed scoping review search will begin in December 2020 and continue throughout January and February 2021. The search will be conducted according to the three steps of Joanna Briggs Institute (JBI) methodology for scoping reviews³¹:

1. The CINAHL and PsychInfo databases were initially searched to identify papers on the topic. The search terms used for this initial search are provided as

Extended data (Table 1)²⁷. Text words contained in the titles and abstract of included articles and within the index terms (describing the articles) were used to develop a full search strategy for CINAHL complete database (Table 2, *Extended data*²⁷). This search strategy (including its identified keywords and index terms) will be adapted for all the information sources included in this scoping review.

2. A second search will be undertaken across all included databases, namely: Ovid MEDLINE, Embase, CINAHL, JBI Evidence Synthesis, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, PsycINFO and Scopus. This will be done using all the identified keywords and index terms. Grey literature databases will also be searched (Open Grey, reports, dissertations, theses databases and databases of conference abstracts (e.g. Scopus (for conference proceedings only), ETHOS, ProQuest) for national and international strategies and policies as well as standards and guidance documents.
3. The reference lists of the articles and reports identified and included in the review will be searched for further studies. If warranted, authors of included articles will be contacted for further information.

Evidence selection

The selection of evidence to be included in the scoping review will be carried out independently by two reviewers. Following the search, all identified records will be reviewed and duplicates excluded. Thereafter, titles and abstracts will be assessed for inclusion. The remaining studies full texts will be screened against the inclusion criteria and the reasons for exclusion will be identified and recorded. This process will be carried out using the reference management software 'Rayyan'³². Any discrepancies that may arise regarding evidence selection will be resolved through discussion and consensus with a third reviewer.

Data extraction and reporting

Data will be extracted independently by two reviewers, conflicts resolved by consensus or discussion with a third reviewer. A data extraction tool developed by the reviewers will be piloted using four studies from a preliminary literature search on the research topic (Table 3, *Extended data*). The review pairs will discuss the usability of the tool, any possible additions or changes in order to evaluate and/or modify the tool prior to adoption. Any adaptations to the tool will be documented clearly. Thereafter, the data extraction tool will be utilised independently by the two reviewers during appraisal of the evidence base.

The data extraction tool will include the following details:

- Names of the authors, year of publication, country of origin,

- Medication usage: prevalence, types, indications, dosage, duration of use, setting (RQ1 and RQ2)
- Medication effectiveness: clinical effectiveness measures, side effects, drug interactions, experiences of patients (RQ3)
- Medication management intervention designs: population, type of intervention, any comparator and setting, healthcare professionals involved (RQ4 and RQ5)
- Outcomes of medication management programs (RQ4 and RQ5)

Reporting of key information from the chosen studies will be performed using Table 3 provided as *Extended data* (Table 3)²⁷. The chart data will detail the aim of study, methodology, intervention, outcomes, findings and limitations. We will use the data to describe the context of studies selected, how relevant outcomes were measured and any reported limitations or quality issues

Data presentation

The results will be mapped and presented in relation to each of the research questions. The results of the review will be presented in a narrative form. As necessary, tables and diagrams will be utilized to illustrate findings augmented by narrative text. Results will be reported and presented in accordance with [PRISMA-ScR reporting guidance](#) and the [PRISMA flow diagram](#)³⁰.

Study status

The search is currently underway across databases outlined in methods section. This search will take place from December 2020 and continue throughout January and February 2021.

Data availability

Underlying data

No underlying data are associated with this article.

Extended data

Zenodo: Management of psychotropic medications in adults with intellectual disability: a scoping review protocol. <https://doi.org/10.5281/zenodo.5752729>.

This project contains the following extended data in the document 'Extended Data.docx':

- Table 1: Preliminary Search
- Table 2: Full search strategy
- Table 3: Data extraction tool

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](#) (CC-BY 4.0).

References

- American Psychiatric Association: **Diagnostic and Statistical Manual of Mental Disorders**. FEA, VA: American Psychiatric Association, 2013. [Reference Source](#)
- Maulik PK, Mascarenhas MN, Mathers CD, *et al.*: **Prevalence of intellectual disability: a meta-analysis of population-based studies**. *Res Dev Disabil*. 2011; **32**(2): 419–36. [PubMed Abstract](#) | [Publisher Full Text](#)
- Sheehan R, Hassiotis A, Walters K, *et al.*: **Mental illness, challenging behaviour, and psychotropic drug prescribing in people with intellectual disability: UK population based cohort study**. *BMJ*. 2015; **351**: h4326. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Whitaker S, Read S: **The Prevalence of Psychiatric Disorders among People with Intellectual Disabilities: An Analysis of the Literature**. *J Appl Res Intellect Disabil*. 2006; **19**(4): 330–345. [PubMed Abstract](#) | [Publisher Full Text](#)
- Buckles J, Luckasson R, Keefe E: **A Systematic Review of the Prevalence of Psychiatric Disorders in Adults With Intellectual Disability, 2003–2010**. *J Ment Health Res Intellect Disabil*. 2013; **6**(3): 181–207. [PubMed Abstract](#) | [Publisher Full Text](#)
- McCarthy J, Boyd J: **Mental health services and young people with intellectual disability: is it time to do better?** *J Intellect Disabil Res*. 2002; **46**(Pt 3): 250–6. [PubMed Abstract](#) | [Publisher Full Text](#)
- Gulliford M, Figueroa-Munoz J, Morgan M, *et al.*: **What does 'access to health care' mean?** *J Health Serv Res Policy*. 2002; **7**(3): 186–8. [PubMed Abstract](#) | [Publisher Full Text](#)
- Manohar H, Subramanian K, Kandasamy P, *et al.*: **Diagnostic Masking and Overshadowing in Intellectual Disability-How Structured Evaluation Helps**. *J Child Adolesc Psychiatr Nurs*. 2016; **29**(4): 171–176. [PubMed Abstract](#) | [Publisher Full Text](#)
- Trollor JN, Salomon C, Franklin C: **Prescribing psychotropic drugs to adults with an intellectual disability**. *Aust Prescr*. 2016; **39**(4): 126–130. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Ahlström G, Axmon A, Sandberg M, *et al.*: **Specialist psychiatric health care utilization among older people with intellectual disability - predictors and comparisons with the general population: a national register study**. *BMC Psychiatry*. 2020; **20**(1): 70. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Perry BI, Cooray SE, Mendis J, *et al.*: **Problem behaviours and psychotropic medication use in intellectual disability: a multinational cross-sectional survey**. *J Intellect Disabil Res*. 2018; **62**(2): 140–149. [PubMed Abstract](#) | [Publisher Full Text](#)
- Robertson J, Emerson E, Gregory N, *et al.*: **Receipt of psychotropic medication by people with intellectual disability in residential settings**. *J Intellect Disabil Res*. 2000; **44**(Pt 6): 666–76. [PubMed Abstract](#) | [Publisher Full Text](#)
- Royal College of Psychiatrists: **Challenging behaviour: a unified approach**. London: Royal College of Psychiatrists BPSaRCoSaLTCR. [Reference Source](#)
- Tanwar M, Lloyd B, Julies P: **Challenging behaviour and learning disabilities: prevention and interventions for children with learning disabilities whose behaviour challenges: NICE guideline 2015**. *Arch Dis Child Educ Pract Ed*. 2017; **102**(1): 24–27. [PubMed Abstract](#) | [Publisher Full Text](#)
- Deutsch SI, Burket JA: **Psychotropic medication use for adults and older adults with intellectual disability; selective review, recommendations and future directions**. *Prog Neuropsychopharmacol Biol Psychiatry*. 2021; **104**: 110017. [PubMed Abstract](#) | [Publisher Full Text](#)
- Ali A, Blickwedel J, Hassiotis A: **Interventions for challenging behaviour in intellectual disability**. *Adv Psychiatr Treat*. 2014; **20**(3): 184–192. [PubMed Abstract](#) | [Publisher Full Text](#)
- Emerson E, Kiernan C, Alborz A, *et al.*: **The prevalence of challenging behaviors: a total population study**. *Res Dev Disabil*. 2001; **22**(1): 77–93. [PubMed Abstract](#) | [Publisher Full Text](#)
- National Collaborating Centre for Mental Health (UK): **Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges**. NICE, 2015. [PubMed Abstract](#)
- Molyneux P, Emerson E, Caine A: **Prescription of Psychotropic Medication to People with Intellectual Disabilities in Primary Health-care Settings**. *J Appl Res Intellect Disabil*. 1999; **12**(1): 46–57. [PubMed Abstract](#) | [Publisher Full Text](#)
- Deb S, Sohanpal SK, Soni R, *et al.*: **The effectiveness of antipsychotic medication in the management of behaviour problems in adults with intellectual disabilities**. *J Intellect Disabil Res*. 2007; **51**(Pt 10): 766–77. [PubMed Abstract](#) | [Publisher Full Text](#)
- Matson JL, Neal D: **Psychotropic medication use for challenging behaviors in persons with intellectual disabilities: an overview**. *Res Dev Disabil*. 2009; **30**(3): 572–86. [PubMed Abstract](#) | [Publisher Full Text](#)
- de Leon J, Greenlee B, Barber J, *et al.*: **Practical guidelines for the use of new generation antipsychotic drugs (except clozapine) in adult individuals with intellectual disabilities**. *Res Dev Disabil*. 2009; **30**(4): 613–69. [PubMed Abstract](#) | [Publisher Full Text](#)
- Sheehan R, Hassiotis A: **Reduction or discontinuation of antipsychotics for challenging behaviour in adults with intellectual disability: a systematic review**. *Lancet Psychiatry*. 2017; **4**(3): 238–256. [PubMed Abstract](#) | [Publisher Full Text](#)
- Emerson E: **Challenging Behaviour: Analysis and Intervention in People with Learning Difficulties**. Cambridge University Press, Cambridge. 1995. [Reference Source](#)
- Sullivan WF, Berg JM, Bradley E, *et al.*: **Primary care of adults with developmental disabilities: Canadian consensus guidelines**. *Can Fam Physician*. 2011; **57**(5): e541–68. [PubMed Abstract](#) | [Free Full Text](#)
- Marshall T: **Audit of the use of psychotropic medication for challenging behaviour in a community learning disability service**. *Psychiatr Bull*. 2004; **28**(12): 447–450. [PubMed Abstract](#) | [Publisher Full Text](#)
- Deb S, Unwin G, Deb T: **Characteristics and the trajectory of psychotropic medication use in general and antipsychotics in particular among adults with an intellectual disability who exhibit aggressive behaviour**. *J Intellect Disabil Res*. 2015; **59**(1): 11–25. [PubMed Abstract](#) | [Publisher Full Text](#)
- Deb S, Unwin GL: **Psychotropic medication for behaviour problems in people with intellectual disability: A review of the current literature**. *Curr Opin Psychiatry*. 2007; **20**(5): 461–6. [PubMed Abstract](#) | [Publisher Full Text](#)
- Monaghan R, O'Dwyer M, Luus R, *et al.*: **The relationship between antiepileptic drug load and challenging behaviors in older adults with intellectual disability and epilepsy**. *Epilepsy Behav*. 2021; **122**: 108191. [PubMed Abstract](#) | [Publisher Full Text](#)
- Tricco AC, Lillie E, Zarin W, *et al.*: **PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation**. *Ann Intern Med*. 2018; **169**(7): 467–473. [PubMed Abstract](#) | [Publisher Full Text](#)
- Peters MDJ, Munn Z, Tricco AC, *et al.*: **Scoping Reviews (2020 version)**. In: Aromataris E, Munn Z (Editors). *JBri Manual for Evidence Synthesis*, JBri, 2020. [Reference Source](#)
- Ouzzani M, Hammady H, Fedorowicz Z, *et al.*: **Rayyan-a web and mobile app for systematic reviews**. *Syst Rev*. 2016; **5**(1): 210. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)

Open Peer Review

Current Peer Review Status: ? ✓ ?

Version 1

Reviewer Report 08 October 2021

<https://doi.org/10.21956/hrbopenres.14295.r30244>

© 2021 Harley D. This is an open access peer review report distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

? **David Harley** 

UQ Centre for Clinical Research, The University of Queensland, Herston, Qld, Australia

This is a well-written protocol for a study addressing a very important topic. The article describes the methods for a scoping review of the use of psychotropic medications in people with intellectual disabilities. The authors' aim is "To explore the existing evidence base regarding the prescription and management of psychotropic medications in adults with ID". The proposed review will encompass the types of drugs prescribed, indications and evidence base, guidelines for management, and protocols for cessation. The topic chosen is important because the health of people with an intellectual disability is poor and because the inappropriate use of psychotropic medications significantly contributes to this poor health status. In addition, clinicians who manage people with intellectual disabilities need evidence for their prescribing, and this review has the potential to significantly contribute here.

The scope for the review is quite broad. It would be good to have more information on words to be used in the search because this would allow replication. Important context for this work is the definition of challenging behaviour along with its precipitants. This is because prescribing, and particularly inappropriate prescribing, is often a response to challenging behaviour. One of the research questions is, "What is the clinical indication(s) for prescription of such medications?", and it is well recognised that challenging behaviour is often cause for prescribing. An acknowledgement, because this relates to some of the research questions, of the myriad precipitants for challenging behaviour is crucial. Challenging behaviour is a means of communication, and many of the causes, such as sexual abuse, constipation, and pain, are not appropriately managed with psychotropic medications.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Adult developmental disability medicine, with a particular interest in psychotropic prescribing.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 03 Dec 2021

Ashley Costello, University of Limerick, Castletroy, Ireland

Dear Editor and Colleagues,

Thank you all for reviewing our paper. Your comments have been very helpful. We appreciate the opportunity to respond and have addressed all comments, point-by-point.

Reviewer 3:

David Harley Peer Review (Approved with Reservations)

Reviewer: This is a well-written protocol for a study addressing a very important topic. The article describes the methods for a scoping review of the use of psychotropic medications in people with intellectual disabilities. The authors' aim is "To explore the existing evidence base regarding the prescription and management of psychotropic medications in adults with ID". The proposed review will encompass the types of drugs prescribed, indications and evidence base, guidelines for management, and protocols for cessation. The topic chosen is important because the health of people with an intellectual disability is poor and because the inappropriate use of psychotropic medications significantly contributes to this poor health status. In addition, clinicians who manage people with intellectual disabilities need evidence for their prescribing, and this review has the potential to significantly contribute here.

Reviewer: The scope for the review is quite broad. It would be good to have more information on words to be used in the search because this would allow replication.

Response: The search terms are provided in Table 1 in the [extended data](#).

Reviewer: Important context for this work is the definition of challenging behaviour along with its precipitants. This is because prescribing, and particularly inappropriate prescribing, is often a response to challenging behaviour. One of the research questions is, "What is the clinical indication(s) for prescription of such medications?", and it is well recognised that challenging behaviour is often cause for prescribing. An acknowledgement, because this

relates to some of the research questions, of the myriad precipitants for challenging behaviour is crucial. Challenging behaviour is a means of communication, and many of the causes, such as sexual abuse, constipation, and pain, are not appropriately managed with psychotropic medications.

Response: We have revised our definition of challenging behaviour in the introduction to as follows: "As defined by The Royal College of Psychiatrists, challenging behaviour is behaviour of such an intensity, frequency or duration as to threaten the quality of life and/or the physical safety of the individual or others and is likely to lead to responses that are restrictive, aversive or result in exclusion (13). It may include behaviours of a destructive nature, such as aggression, violence and self-injury (14-16). Challenging behaviour can also be an attempt to communicate unmet needs, which require identification of causes and promotion of positive behaviours and addressing social needs."

Competing Interests: No competing interests were disclosed.

Reviewer Report 13 September 2021

<https://doi.org/10.21956/hrbopenres.14295.r30254>

© 2021 Roy A. This is an open access peer review report distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.



Ashok Roy 

¹ Coventry and Warwickshire Partnership NHS Trust, Coventry, UK

² University of Warwick, Coventry, UK

³ Health Education England, London, UK

This scoping review aims to investigate available literature, find gaps, and recommend future studies and systematic reviews. Additional keywords may include "overmedication" and STOMP (Stopping Overmedication in People with Learning Disability), a national initiative in the UK that has been the subject of recent research and audit.

The authors are looking for outcome reporting on "practices or behaviours among ID population, their carers or their prescribers". This is very broad. It would be clearer if the term "behaviours" was used in relation to the ID population and "practices" for prescribers or even non-prescribing professionals. This specific issue is not covered by the Research Questions.

The protocol is clearly laid out and the references are relevant and recent. I found *Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach* by Munn, Z. *et al.* BMC Medical Research Methodology 18, 143 (2018) ¹ useful to understand why the authors had opted for carrying out a scoping review rather than carrying out a systematic review.

References

1. Munn Z, Peters M, Stern C, Tufanaru C, et al.: Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Medical Research Methodology*. 2018; **18** (1). [Publisher Full Text](#)

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Intellectual Disability Psychiatry

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 03 Dec 2021

Ashley Costello, University of Limerick, Castletroy, Ireland

Dear Editor and Colleagues,

Thank you all for reviewing our paper. Your comments have been very helpful. We appreciate the opportunity to respond and have addressed all comments, point-by-point.

Reviewer 2

Ashok Roy Peer Review (Approved)

Reviewer: This scoping review aims to investigate available literature, find gaps, and recommend future studies and systematic reviews. Additional keywords may include "overmedication" and STOMP (Stopping Overmedication in People with Learning Disability), a national initiative in the UK that has been the subject of recent research and audit.

Response: Thank you. We have added these keywords to our search.

Reviewer: The authors are looking for outcome reporting on "practices or behaviours among ID population, their carers or their prescribers". This is very broad. It would be clearer if the term "behaviours" was used in relation to the ID population and "practices" for prescribers or even non-prescribing professionals. This specific issue is not covered by the Research Questions.

Response: We have now amended our outcomes to reflect this suggestion;

“- Any qualitative or quantitative outcome reporting on psychotropic medication use and behaviours among the population with ID.

- Any qualitative or quantitative outcome reporting on psychotropic medication safety measures (adverse drug event, adverse drug reaction, medication error, adherence, compliance, consumption, drug-related problems)

- Any professional practices by health care providers in relation to managing psychotropics in the population with ID”

Reviewer: The protocol is clearly laid out and the references are relevant and recent. I found Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach by Munn, Z. et al. BMC Medical Research Methodology 18, 143 (2018) ¹ useful to understand why the authors had opted for carrying out a scoping review rather than carrying out a systematic review.

Response: We have added further justification for the scoping review to the introduction as follows: “As we are also interested in dose reductions of psychotropic medications and any accompanying psychological or social educational intervention components for challenging behaviours, we choose to undertake a scoping review rather than a systematic review to include de-prescribing studies and heterogeneous study methodologies.”

Competing Interests: No competing interests were disclosed.

Reviewer Report 06 September 2021

<https://doi.org/10.21956/hrbopenres.14295.r29800>

© 2021 Ramerman L. This is an open access peer review report distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.



Lotte Ramerman 

Netherlands Institute for Health Services Research, Utrecht, The Netherlands

The scoping review is focused on collecting and reviewing available literature on the subject of prescribing psychotropic medications to people with ID, including for mental illness and challenging behaviors. Furthermore, it will search for literature on managing the medication and strategies to discontinue.

The authors provided a clearly written protocol on a very important topic. A clear description of all available knowledge will be very valuable.

Some general remarks

- I would suggest not using terms as ID patient but stick to “people with ID”.
- I would suggest using fewer abbreviations to improve readability. Also, check the text for not intentional abbreviations, such as “meds”.

Rationale and objectives

- I feel some of the review has been done (partly) before, but some time ago. Maybe the authors can refer to this and state that they are providing an update. For example, Deb, S., & Unwin, G. L. (2007). Psychotropic medication for behaviour problems in people with intellectual disability: A review of the current literature. *Current Opinion in Psychiatry*, 20(5), 461-466¹, or the systematic reviews by Brylewski and Duggan².
- The description of challenging behavior is kind of narrow, focusing on aggression and self-injury. This does not consider other challenging behaviors such as stereotypical behaviors, withdrawn behavior, or lethargy. Challenging behavior may be defined as behavior of such an intensity, duration, or frequency that the behavior is a danger to the physical safety of the person or others. Furthermore, these behaviors could lead to exclusion from the community.
- Furthermore, a description of the underlying issues that are related to challenging behaviors would be useful. These can be mental illnesses, but can also be related to physical complaints, problems in the environment of the person, etc.
- “Psychotropic medications are commonly prescribed amongst adults and older adults with ID” needs a reference. Furthermore, psychotropic medications are not just prescribed to adults with ID, but also to children and adolescents. Why did you specifically focus on adults and older adults?
- Statements in the introduction, such as “However, due to the paucity of research regarding psychotropic discontinuation”, are a little too strong as there is research available, especially on the discontinuation of antipsychotic drugs. Furthermore, how does this statement relate to your objective in which you aim to review studies on this topic?
- Another example: “Despite a small body of research on this topic, the advice to health care professionals remains unclear”. This is much more nuanced. There are guidelines on prescribing and discontinuation of psychotropic drugs and there is research available. However, the situation of people with ID and challenging behaviors who use psychotropic drugs is often very complex.
- The focus on mental illness and/or challenging behavior remains unclear from the objective. Maybe the authors could be a little more explicit in their objectives.

Study design

- Why did the authors decide on a scoping review and not a systematic review?

Methods

- I am not familiar with the “three steps of Joanna Briggs Institute (JBI) methodology for scoping reviews”. Can you provide a reference?
- A data extraction tool developed by the reviewers is mentioned, including that it is piloted in four studies. However, it remains unclear what the relation is between the pilot and the

scoping review. And, the tool needs references.

- The description of the data extraction tool in the article does not include a description of the type of studies and the quality of the studies reviewed. However, Table 3 does. A little more information on how literature is reviewed and included in the reporting would be useful.
- Furthermore, check for double information.

References

1. Deb S, Unwin GL: Psychotropic medication for behaviour problems in people with intellectual disability: a review of the current literature. *Curr Opin Psychiatry*. 2007; **20** (5): 461-6 [PubMed Abstract](#) | [Publisher Full Text](#)
2. Brylewski J, Duggan L: Antipsychotic medication for challenging behaviour in people with learning disability. *Cochrane Database Syst Rev*. 2004. CD000377 [PubMed Abstract](#) | [Publisher Full Text](#)

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Partly

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Health Services Research, People with Intellectual Disabilities, Antipsychotic Drugs, Primary (out-of hours) Care

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 03 Dec 2021

Ashley Costello, University of Limerick, Castletroy, Ireland

Dear Editor and Colleagues,

Thank you all for reviewing our paper. Your comments have been very helpful. We appreciate the opportunity to respond and have addressed all of your comments below, point-by-point.

Reviewer 1

Lotte Ramerman Peer Review (Approved with reservations)

The scoping review is focused on collecting and reviewing available literature on the subject of prescribing psychotropic medications to people with ID, including for mental illness and challenging behaviors. Furthermore, it will search for literature on managing the medication and strategies to discontinue.

The authors provided a clearly written protocol on a very important topic. A clear description of all available knowledge will be very valuable.

Some general remarks

Reviewer: I would suggest not using terms as ID patient but stick to “people with ID”.

Response: Many thanks for highlighting this to us – edits have been made to adopt this suggestion throughout our protocol.

Reviewer: I would suggest using fewer abbreviations to improve readability. Also, check the text for not intentional abbreviations, such as “meds”.

Response: We have since removed unnecessary abbreviations and have corrected any unintentional use of “meds”.

Rationale and objectives

Reviewer: I feel some of the review has been done (partly) before, but some time ago. Maybe the authors can refer to this and state that they are providing an update. For example, Deb, S., & Unwin, G. L. (2007). Psychotropic medication for behaviour problems in people with intellectual disability: A review of the current literature. *Current Opinion in Psychiatry*, 20(5), 461-466¹, or the systematic reviews by Brylewski and Duggan².

Response: We have now included reference to this paper in our introduction and one other relevant review that we are aware of.

Reviewer: The description of challenging behavior is kind of narrow, focusing on aggression and self-injury. This does not consider other challenging behaviors such as stereotypical behaviors, withdrawn behavior, or lethargy. Challenging behavior may be defined as behavior of such an intensity, duration, or frequency that the behavior is a danger to the physical safety of the person or others. Furthermore, these behaviors could lead to exclusion from the community.

Furthermore, a description of the underlying issues that are related to challenging behaviors would be useful. These can be mental illnesses, but can also be related to physical complaints, problems in the environment of the person, etc.

Response: Thank you for this helpful suggestion. We have amended our previous definition to a broader, more descriptive definition of challenging behaviour.

Reviewer: "Psychotropic medications are commonly prescribed amongst adults and older adults with ID" needs a reference. Furthermore, psychotropic medications are not just prescribed to adults with ID, but also to children and adolescents. Why did you specifically focus on adults and older adults?

Response: Our plan is to develop an intervention targeting the adult population with ID in the first instance. For that reason, our search focuses on adults. Our future research intends to broaden this to the children and adolescent population.

Reviewer: Statements in the introduction, such as "However, due to the paucity of research regarding psychotropic discontinuation", are a little too strong as there is research available, especially on the discontinuation of antipsychotic drugs. Furthermore, how does this statement relate to your objective in which you aim to review studies on this topic?

Another example: "Despite a small body of research on this topic, the advice to health care professionals remains unclear". This is much more nuanced. There are guidelines on prescribing and discontinuation of psychotropic drugs and there is research available. However, the situation of people with ID and challenging behaviors who use psychotropic drugs is often very complex.

The focus on mental illness and/or challenging behavior remains unclear from the objective. Maybe the authors could be a little more explicit in their objectives.

Response: We have edited our study aim to more explicitly illustrate the aim of the scoping review and objectives:

"This aim of this scoping review is to investigate the existing literature on the use of psychotropic medications within the ID cohort to manage challenging behaviour".

"In particular, this review aims to identify what psychotropic medications are prescribed to adults with ID, why they are prescribed to this patient cohort and how these medications are managed over the long term. This will be carried out by including interventions that aim to achieve dose reduction or complete cessation of psychotropics and to identify the associated risks and benefits that accompany this reduction/cessation. As we are also interested in dose reductions of psychotropic medications and any accompanying psychological or social educational intervention components for challenging behaviours, we choose to undertake a scoping review rather than a systematic review to include de-prescribing studies."

Study design

Reviewer: Why did the authors decide on a scoping review and not a systematic review?

Response: We have added further justification for the scoping review to the introduction as

follows:

“As we are also interested in dose reductions of psychotropic medications and any accompanying psychological or social educational intervention components for challenging behaviours, we choose to undertake a scoping review rather than a systematic review to include de-prescribing studies and heterogeneous study methodologies.”

Methods

Reviewer: I am not familiar with the “three steps of Joanna Briggs Institute (JBI) methodology for scoping reviews”. Can you provide a reference?

Response: We have now included the following reference in our protocol:

Peters MDJ, Godfrey C, McInerney P, Munn Z, Tricco AC, Khalil, H. Chapter 11: Scoping Reviews (2020 version). In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis*, JBI, 2020. Available from <https://synthesismanual.jbi.global>.
<https://doi.org/10.46658/JBIMES-20-12>

Reviewer: A data extraction tool developed by the reviewers is mentioned, including that it is piloted in four studies. However, it remains unclear what the relation is between the pilot and the scoping review. And, the tool needs references.

Response: We have added references to the tool and explained the term ‘4 pilot studies’. “A data extraction tool developed by the reviewers will be piloted using four studies from a preliminary literature search on the research topic (Table 3, Extended data)”.

Reviewer: The description of the data extraction tool in the article does not include a description of the type of studies and the quality of the studies reviewed. However, Table 3 does. A little more information on how literature is reviewed and included in the reporting would be useful.

Response: We will chart the study components and then map them to the research questions. The charting will include the methodology and limitations of the studies, which will allow us to comment on methodological strengths and weaknesses of the existing body of research. We have added some more detail to the ‘Data extraction and reporting section’: “The chart data will detail the aim of study, methodology, intervention, outcomes, findings and limitations. We will use the data to describe the context of studies selected, how relevant outcomes were measured and any reported limitations or quality issues.”

Competing Interests: No competing interests were disclosed.