








STUDY PROTOCOL

REVISED

Examining Quality, Use and Impact of Psychotropic (Use) in older adults with intellectual disabilities (EQUIP): study protocol [version 2; peer review: 1 approved]

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Abstract

Widespread, and sometimes inappropriate use of psychotropics in adults with intellectual disability has been an international concern. These medicines have been used to treat mental health conditions, but also, controversially, some types of behaviours not necessarily associated with the diagnosis or in the absence of a relevant diagnosis. Results from the Intellectual Disability Supplement to the Irish Longitudinal Study on Ageing (IDS-TILDA) study of older adults with intellectual disability in Ireland revealed that 60% were taking psychotropics in 2010. In the intervening decade changes in regulations, policy, and increased decongregation of people with intellectual disability have taken place likely influencing the use of psychotropics. The HSE National Clinical Programme for People with Disability (NCPDD) established in the 2020 has medicines optimisation as a key priority. Existing multi-wave data from the IDS-TILDA study and the HSE national prescribing database offers an opportunity to better understand psychotropic use and prescribing patterns. This is a novel collaboration on lived experience, research, practice and policy.

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1

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[view](#)

1. **Danielle Adams** , University of Warwick, Coventry, UK

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

The aim of this research is to examine the quality and trends of psychotropic use of older adults with intellectual disability over a ten-year period in Ireland to evaluate the effects of and to inform both practice and policy to optimise medicines use and health outcomes.

Health and medication data from ten years (four waves) of the IDS-TILDA study and corresponding medicines data from the HSE-PCRS prescribing database are available. Descriptive and longitudinal analysis will examine association between long-term psychotropic use, changes in trends of use, and the impact of decongregation on medicines use.

This research will inform the development of national guidance on medicines optimisation for older people with intellectual disability and has the potential to change prescribing practices and improve health and wellbeing for older people with intellectual disability.

Keywords

polypharmacy, psychotropic drugs, intellectual disability, mental disorders, population characteristics

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REVISED Amendments from Version 1

This version of the article addresses inconsistencies identified by the reviewer, for example, 'behaviours which challenge' and 'behaviours that challenge' were both used in the original submission. This latest version has corrected all forms to 'behaviours that challenge'. Similarly, 'disabilities' has been amended to 'disability' throughout the article.

We thank the reviewer for their time and comments.

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

Introduction

The greater use of psychotropic medicines in adults with intellectual disability, sometimes in the absence of an emotional/nervous or psychiatric condition, remains controversial and increases risk of medication-related harm¹⁻⁶. Older adults with intellectual disability who have mental health conditions represent one of the most vulnerable groups in society⁷. While appropriate use of psychotropic medicines to treat mental illness is critical, overuse of antipsychotics in particular for behaviours that challenge in the absence of a mental health diagnosis has been an international concern. There are also related physical health and mortality concerns that optimal medicines management may avoid. Health needs for people with intellectual disability are already often unmet and unrecognized, and poorer health status may be avoidable⁸⁻¹¹. In particular, the use of psychotropic medications have anticholinergic effects which may cause cognitive impairment, constipation and sedation. Mortality for people with intellectual disability in Ireland is four times higher than for the general population¹².

There has been evidence in Ireland and internationally of inappropriate psychotropic prescribing practices in some institutional settings for people with intellectual disability¹³. Almost 60% of people with intellectual disability reported use of psychotropics and 40% psychotropic polypharmacy within the first wave of the Intellectual Disability Supplement to Irish Longitudinal study on Ageing (IDS-TILDA), ten years ago². The level of intraclass polypharmacy (2+ medicines from the same class) was greatest for antipsychotics (25.6%, 82/319 antipsychotics users) and anxiolytics/hypnotics (26.7%; 59/221 anxiolytics/hypnotics users)². Excessive polypharmacy (10+ psychotropic medicines) was reported by 158/736, 21.5% of people with intellectual disability, compared to 2% in the older adult general population in the TILDA study¹⁴. Some of this prescribing may be historical and reflects that medication are often utilised for decades. In the UK, the Winterbourne View report highlighted serious and systemic findings relating to psychotropic use in residential institutions. As a result, "Stopping overmedication of people with a learning disability, autism or both" (STOMP) was developed by the National Health Service (NHS) England; a multidisciplinary collaboration of patients, carers and healthcare professionals¹⁵. There has been no similar initiative to date in Ireland.

In the past decade deinstitutionalisation in Ireland has been ongoing. The "Time to Move on from Congregated Settings Report" established in 2011 stated that approximately 4,000 people lived in congregated settings (ten or more people living together)¹⁵. The vision of the report set out that "all individuals currently residing in congregated settings will have the opportunity or right to move to a home of their choice in the community"¹⁵. Some evidence suggests that changes in medicines occur following a change of setting. Findings in relation to the influence of place and change of setting on medication use remain inconclusive, with some research suggesting that medication use may increase after community placement^{16,17}. The specific impact on medicines use in Ireland has yet to be investigated.

The ability to use descriptive and longitudinal methods with existing medicines data in IDS-TILDA to examine the quality, impact and trends of psychotropic prescribing over a decade, will generate evidence to support optimising prescribing development of national guidelines for medicines use. Linkage to the Health Service Executive – Primary Care Reimbursement Service (HSE-PCRS) dispensing data will enrich the analyses by providing additional information on length of exposure to medicines and trends of use, dispensed combinations and adherence issues.

The aim of this study is to examine the quality and trends of psychotropic use of older adults with intellectual disability over a ten-year period in Ireland to inform practice and policy and optimise medicines use and health outcomes. The specific objectives of this study are:

- To examine the effects of psychotropic medicines on cognitive and physical function in older adults with intellectual disability
- Assess the change in patterns in psychotropic medicines use among older adults with intellectual disabilities over a decade
- Assess the influence of change in place of residence on psychotropic use patterns in older adults with intellectual disability over a decade
- Examine the differences in psychotropic prescribing patterns for those age 40–49 years in 2009/2010 and those aged 40–49 years who were newly recruited in IDS-TILDA Wave 4 in 2019/2020
- Involve persons with intellectual disability and key stakeholders in a useful and informative manner from inception to dissemination of the project. This will ensure the focus of the project is shaped by their involvement and the findings prioritized to influence practice and policy to improve their healthcare.

Methods

This retrospective cohort study uses medicines, health and demographic data from four waves of the IDS-TILDA study

and data provided from the National Pharmacy Claims database, the HSE-PCRS. The IDS-TILDA was established as a supplement to The Irish Longitudinal Study on Ageing (TILDA)¹⁸. The study is the first of its kind in Europe and is the only study able to directly compare the ageing of people with intellectual disabilities with the general ageing population¹⁸.

Population

The study follows a representative sample of older adults with intellectual disability (aged >40 years) to determine the influences of ageing, health and medicines use. There have been four data collection waves (every three years) since 2010. IDS-TILDA had a degree of attrition, due to death of 105 participants through the first three waves of the study, but a low level of withdrawal, with 39 participants who withdrew. To re-address representativeness, the sample was refreshed at Wave 4. Refreshing the sample at Wave 4 included replacing the age 40–50-year-old cohort who were now aged >50 years by Wave 4. As a result, there were 135 new participants recruited at Wave 4 aged 40–49 years¹⁹. Finally, the total number of participants in Wave 4 was 739.

People with intellectual disability represent a vulnerable population and some may not have sufficient understanding of study participation. There is a need for increased safeguards around consent and informed consent. This study therefore relies upon a Data Protection Impact Assessment (DPIA) and a successful application to the Health Research Consent Declaration Committee (HRCDC) for a Consent Declaration to include some participants with intellectual disability who lacked the capacity to provide consent directly. Ethical approval was granted by TCD Faculty of Sciences Research Ethics Committee on 23rd January 2019 for Wave 4. Ethics committees for all involved service providers also granted approval. The HRCDC granted a full Consent Declaration for the study in December 2019, facilitating the inclusion of proxy-consented participants. The data to be used here was collected under these approvals and similar approvals for previous waves.

Sources of data

IDS-TILDA. At each wave participants and/or proxy completed a pre-interview questionnaire (PIQ) and had a face-to-face computer-assisted personal interview (CAPI). The PIQ was sent to each participant minimum one week in advance of a face-to-face interview. PIQ reports including medicines data were confirmed at the face-to-face interview to ensure data accuracy and quality and to minimise missing data. All field workers receive specific training before gathering data to ensure data consistency and quality. Given the differing levels of intellectual disabilities and abilities to communicate, different styles of interview are provided in the IDS-TILDA study: a respondent-only interview conducted directly with the individual, a proxy interview completed with the family member or carer most familiar with the person (minimum 6 months) or an interview with the person supported by a family member or carer. A small number of participants required a combination of approaches²⁰.

HSE-PCRS. At Wave 4, 292 IDS-TILDA participants provided consent to link their medical card/Drug Payment Scheme number, and their valid General Medical Scheme (GMS)/Drug Payment Scheme card number, to enable retrieval of their dispensed medicines from the HSE-PCRS. The HSE-PCRS is the national pharmacy dispensing claims database in Ireland for GMS patients and is often used for medicine and health research²¹. HSE-PCRS database records pharmacy claims for monthly dispensed medicines that were prescribed to patients by their general practitioner (GP)²¹. The GMS scheme is a form of public health cover that provides free health services, including prescription medicines to eligible individuals in Ireland (a monthly co-payment per medicine was introduced in 2010). In total, 95% of IDS-TILDA participants are qualified for this benefit. Eligibility is determined by means testing. GMS identifier of IDS-TILDA participants who gave their consent for linkage of their medicines data will serve for medication data extraction from the HSE-PCRS pharmacy claims database. This data will be accessed following appropriate data exchange agreements and Privacy Impact Assessments being signed between Trinity College Dublin and HSE-PCRS. Prescription claims in the database are coded using the World Health Organisation Anatomical Therapeutic Chemical (ATC) classification system. Brand name, strength, quantity, method and unit of administration of each drug dispensed, ingredient costs and pharmacist dispensing fees per item dispensed are recorded. This data will be combined and analysed in Excel.

Work packages

Five work packages (four discrete and one overlapping work package) will ensure that the aim and objectives stated above are achieved. The main project outcomes are presented within the four discrete work packages (see [Table 1](#)), while the explanation of the project outcomes is available in [Table 2](#).

Work package 1 – Examine the effects of psychotropic medicines on cognitive and physical function in older adults with intellectual disability

Study design – The sample population for this work package will be participants who participated in all four waves of IDS-TILDA (n=604). At Wave 2, all IDS-TILDA (n=708) participants were invited to partake in health assessments carried out by a registered nurse in intellectual disability. In total 85% of them (n=602) took part. This included: Quantitative Heel Ultrasound, blood pressure, weight, waist-to-hip ratio, grip strength, timed-up and go. Similar assessments were repeated in Wave 4. In total, at Wave 4, 274 participants were invited to participate in a health assessment fair, of which 260 participated. This lower number was due to the impact of coronavirus disease 2019 (COVID-19) as the health fair had to be ceased. These objective measures included the same measurements as with Wave 2 with additional measurements including balance assessment, activity monitoring, sit to stand assessment, calf measurement, Kardia ECG, and blood samples.

Indicators – Demographics including age, level of intellectual disability, cause of Intellectual disability (Down

Table 1. Overview of the main project outcomes across the work packages.

Work package title	Main outcome
Work package 1: Examine the effects of psychotropic medicines on cognitive and physical function in older adults with intellectual disability	The effects of psychotropic medicines on cognitive and physical function in older adults with intellectual disability in four time points over ten-year period of time
Work package 2: Assess the change in patterns of psychotropic medicines use among older adults with intellectual disabilities over a decade	Change in prevalence and pattern of psychotropic medicines and psychotropic polypharmacy, and their relationship to mental health diagnosis and behaviours that challenge at two time points (Wave 1 and Wave 4)
Work package 3: Assess the influence of change in place of residence on psychotropic use patterns in older adults with intellectual disability over a decade	Change in psychotropic medicines use following a change in place of residence over time
Work package 4: Investigate changes in the prevalence and patterns of psychotropic use in two cohorts of adults aged 40–49 years with intellectual disability separated by a 10-year period and associated mental health diagnosis and behaviours that challenge	Prevalence, patterns, and psychotropic use for the two cohorts at two time: points2009/2010 (Wave 1 participants aged 40–49 years) and 2019/2020 (Wave 4 refreshed sample aged 40–49 years)
Work package 5: Ensure patients and key stakeholders' involvement in a meaningful and informative manner from inception to dissemination of the project, to ensure the focus of the project is shaped by their involvement and the findings prioritized to influence practice and policy to improve patient healthcare	Recommendations for practice and policy reinforcement to improve patient healthcare

Table 2. Overview of the project outcomes and explanations.

Outcomes	Explanation
<i>The main outcomes</i>	
Exposure to psychotropic drug	The prevalence of any psychotropic medicine at each time point
The number of psychotropic medicines	The number of medications taken over time
Specific psychotropic medication classes at each time point	The prevalence of psychotropic medication class at each time point: (i) antipsychotic agents, (ii) antidepressants, (iii) anxiolytics/sedative/hypnotics, (iv) mood-stabilising agents (which includes antiepileptics for indications other than epilepsy and lithium)
<i>The secondary outcomes</i>	
Polypharmacy (use of two or more psychotropic agents)	The prevalence of polypharmacy
Total daily doses (TDD), Median daily doses (MDD)	Calculation will be based on the available dose information for all psychotropic classes
Intraclass polypharmacy	The prevalence of use of two or more agents from within the same therapeutic class
Interclass polypharmacy will be use of two or more psychotropic medications from different therapeutic classes.	The prevalence of use of two or more agents from different therapeutic class
<i>Explanatory variables</i>	
Predisposing variables	Age, gender, level of ID, living circumstances, co-morbid epilepsy or dementia, other comorbidities, physical health conditions, sleep problems and health perception
Enabling factors	Institutional setting, healthcare access and utilisation, functional and cognitive abilities
Need factors	Reporting a mental health condition, behaviours that challenge, other health problem or comorbidities, a sleep problem, level and type of mental health condition

syndrome/other cause), mobility, living arrangements, sensory and sight difficulties and change in residence between waves will be considered. Cumulative burden of health conditions will be measured using the Functional Comorbidity Index (FCI), addressing confounding by drug indication. Functional status will be assessed by the Barthel Index (BI) Activities of Daily Living. This measures the level of dependence of an individual in ten instrumental activities of daily living (e.g., mobility, using stairs, dressing). It consists of an ordinal scale with range 0–20. A modified form of BI was created for this population²². Behavioural factors, e.g., report of behaviours that challenge will be assessed by specific questions. Mobility will be adjusted for within a regression model relating to falls. The use of objective health measures, such as grip strength, blood pressure, time-up and go, will be considered for inclusion for the sub-population who take part in Waves 2 and 4. Overview of the project outcomes is presented in [Table 1](#) and [Table 2](#).

Analysis - Statistical analysis will be carried out using Excel, SPSS Software Version 27 and STATA. Prevalence of psychotropic use at each wave will be explored and trends will be described. Baseline characteristics of the study population, and longitudinal distribution of the outcome measures at four study timepoints will be described using medians, interquartile ranges (IQR), frequencies, and proportions, as appropriate. This descriptive analysis will inform the approach to the subsequent inferential modelling.

Several multivariate modelling options will be considered to determine the associations between psychotropic exposure and the risk of experiencing each of the outcomes. Outcomes include health status variables measured at Wave 2 and Wave 4 as well as cognitive and physical parameters. These include weighted generalised estimating models, multivariable cox proportional hazard models and Poisson regression. Separate models predicting each of the outcomes will be developed. Models will be adjusted for confounders: baseline age, gender, mobility, number of non-psychotropic medicines reported, baseline cognitive function (TSD), comorbidities (FCI), sociodemographic characteristics. Interactions between psychotropics and confounding variables will be evaluated by testing the statistical significance ($p < 0.05$) of the interaction terms. A variety of adjusted models will be developed to assess the effects of the confounding factors in a group sequential manner. The results will be presented as adjusted odds ratios (OR) and hazard ratios (HR), as appropriate to the model. Kaplan-Meier survival curves will be used to visualise “survival times” (i.e., the time to event, for example, psychotropic exposure and diagnosis of dementia).

The impact of attrition from the waves of the study will be examined due to death, loss to follow up and declined participation. Estimates obtained from the full sample will be compared to a subset of participants who participated in all four time points in the study.

Work package 2 - *Assess the change in patterns of psychotropic medicines use among older adults with intellectual disability over a decade*

Study design – This work package will use data from the IDS-TILDA study from Wave 1 (2009/2010) and Waves 4 (2019/2020). Additionally, in total, 336 participants (45%) provided consent for linkage of their medicines data for two time points [Wave 3 (2016/2017) and Wave 4 (2019/2020)] and a medical card number. The IDS-TILDA study and HSE-PCRS dataset will be linked by matching the eight-digit unique medical card number provided by the participant. Once linkage is complete, all unique identifiers will be removed. Medication data will be extracted from the HSE-PCRS pharmacy claims database by the PCRS on the basis on GMS identifier for each participant in the present study for the specified months of Waves 3 and 4.

Change in prevalence and pattern of psychotropic medicines and psychotropic polypharmacy (use of two or more psychotropic agents), and their relationship to mental health diagnosis and behaviour that challenge behaviour that challenge at two time points (Wave 1 and Wave 4) will be examined. In addition, there will be linkage to HSE-PCRS dispensing data for a subset of Wave 4 participants who consented to linkage and for whom linkage is successful ([Table 1](#)). Analysis of Wave 4 data will be repeated on this subset and compared. The prevalence of any psychotropic medicine at each time point, the number of psychotropic medicines, as well as specific psychotropic medication classes at each time point will be the primary outcomes. Psychotropics will be categorised, as follows: (i) antipsychotic agents, (ii) antidepressants, (iii) anxiolytics/sedative/hypnotics, (iv) mood-stabilising agents (which includes antiepileptics for indications other than epilepsy and lithium)¹⁵. Subcategories of each psychotropic class will be assessed: e.g., atypical/typical antipsychotic. The category “taking any psychotropic medication” will be used. Intra-class polypharmacy will be use of two or more agents from within the same therapeutic class². Inter-class polypharmacy will be use of two or more psychotropic medications from different therapeutic classes. Total daily doses (TDD) and median daily doses (MDD) will be calculated for both cohorts with available dose information.

Indicators – This work package will investigate: (i) mental health diagnosis, (ii) behaviour that challenge and (iii) healthcare utilisation. Diagnosis of epilepsy will be observed as part of antiepileptic drugs use analysis. At each wave, participants were asked “Have you ever received a doctor’s diagnosis of an emotional/nervous or psychiatric condition?” and if yes, “what type of emotional, nervous or psychiatric problems do/does you/she/he have?”. A binary variable will be used (any mental health condition) at both time points (Wave 3 and Wave 4) and mental health conditions categorised². The Behaviour Problem Inventory – Short Form (BPI-S), a validated informant-based questionnaire, was used to record behaviours that challenge at Wave 3 and Wave 4^{23,24}. Participant’s self-reported psychiatric healthcare utilisation will be examined. This includes if the participant is receiving psychiatric treatment or support such as counselling or behaviour support, and if applicable, who the provider of psychiatric treatment or support is (psychiatrists, GP, other). The covariates for this work package will be sex, age

(44–49 years; 50–64 years; 65+ years), level of intellectual disability (mild; moderate; severe/profound), having Down Syndrome or intellectual disability of another aetiology, type of residence (independent, community group home, residential care), change in place of residence. Overview of the project variables is presented in the [Table 1](#).

Analysis – Subject characteristics and reported medicines data will be summarised descriptively with median and IQR for descriptive outcomes and numbers and as percentages for categorical outcomes. The prevalence of any psychotropic medicine at both time points as well as specific psychotropic medication classes will be calculated separately. The prevalence of use by therapeutic class and subclass will be examined and presented for Wave 1 and Wave 4. The median dose of psychotropic medicines for those with dose information at both time points will be compared, and corresponding prevalence of mental health conditions and behaviours that challenge to provide an overall profile of the cohort at both waves, and changes between waves. Analyses will be repeated for participants with linked pharmacy records for Wave 4, with psychotropic use defined according to the medications dispensed in the interview time. The kappa statistics will be used to measure the agreement between the two sources (self-report data and HSE-PCRS data) at Wave 4²⁵. Patient characteristics will be compared for those with and without data linkage²⁵.

Comparison between psychotropic use, mental health conditions, behaviour that challenge, and healthcare utilisation, change of residence, between the two waves will be performed. A Wald test of two prevalence estimates will be carried out. Because use of psychotropic medicines is also associated with age and presence of mental health conditions, changes in the subpopulation age may affect overall prevalence of use. Two-way repeated measures analyses of variance will be used to examine changes in the proportion of individuals taking psychotropic medications and in the number of medications taken over time. Several multivariate modelling approaches will be considered, including logistic regression of imbalanced classes, log linear modelling and decision trees.

The impact of attrition from the waves of the study will be examined due to death, loss to follow up and declined participation. Estimates obtained from the full sample will be compared to a subset of participants who participated in all four time points in the study.

Work package 3 – *Assess the influence of change in place of residence on psychotropic use patterns in older adults with intellectual disability over a decade*

Study design – At each wave of the IDS-TILDA study, participants are categorised as living independently/with family, in a community group home or institution (>10 people). Movers will be identified as those who changed place of residence between each wave and reported this change on both the PIQ and CAPI. In relation to psychotropic medicines, it will be assessed if participants have commenced new

psychotropic medicines or increased/decreased dosage of existing medicines between waves.

Indicators – The covariates in this work package will be sex, level and type of intellectual disability. The confounders are a new mental health diagnosis between each wave, behaviour that challenge, and a new diagnosis of epilepsy and/or dementia.

Analysis – The median (IQR) number of psychotropic medicines will be calculated for participants at waves 1–4 and the change of median psychotropic medicines over time will be assessed. The median doses of psychotropic medicines for those with dose information at each time point will be calculated, and any corresponding prevalence of mental health conditions and behaviours that challenge will be identified to provide an overall profile of the cohort at each wave, and changes between the waves. For each psychotropic medication class there will be four categories between each wave: none (no use at both waves), new (no use at baseline wave and new use at next Wave), discontinued (use at baseline wave and no use at next wave), and recurrent (use at both waves). For those with available dosing data at time points we will also examine change in dose between each time point. A transition matrix will be created to indicate the percentage of cases in each initial category that remain in the category or switch category at each wave. Change in place of residence over time will be assessed in a similar way between each wave i.e., between wave 1 to 2, from wave 2–3 and wave 3–4. There will be four categories: no change in place of residence, community-based move, lateral move, higher support setting move. These will be assigned a score and a change variable will be created with levels and calculated at each wave.

Several models to represent the influence of change in residence on change of psychotropic use will be considered including Multilevel General Estimating Equation modelling and the conditional change model (lagged endogenous variable model). Models will be adjusted for confounders. Models will be estimated accounting for clustering of repeated exposure periods within participants. Analyses will be stratified by age to test whether associations between medicines and outcomes varied by age. For each medication class, four categories of exposure will be considered: none (no use at either wave), new (no use at baseline wave and use at follow-up wave), discontinued (use at baseline wave and no use at follow-up wave), and recurrent (use at both waves).

Work package 4 – *Investigate changes in the prevalence and patterns of psychotropic use in two cohorts of adults aged 40–49 years with intellectual disability separated by a 10-year period and associated mental health diagnosis and behaviours that challenge*

Study design - The samples for this study will be drawn from Waves 1 (2009/2010), and Wave 4 (2019/2020) of the IDS-TILDA study. There were 135 new participants recruited at Wave 4 aged 40–49 years and they will represent the sample for 40–49-year-old cohort at Wave 4 in this study. At Wave 1 in 2009/2010 there were 274 adults aged 40–49 years and these will represent the cohort for Wave 1 of the study.

Indicators – Demographic and clinical characteristics in this work package will be sex, level and type of intellectual disability, type of residence, reported mental health conditions and behaviours that challenge. Health care utilisation in the previous 12 months will be examined (GP visits, outpatient visits, Accident and Emergency visits, hospital admission). Participant’s self-reported psychiatric and psychological healthcare utilisation will be examined at both time points. The availability of easy-read medicines information will also be analysed. The confounders are the reported diagnosis or epilepsy and/or dementia.

Analysis – Descriptive analyses will examine prevalence and patterns of psychotropic use, including subcategories for the two cohorts separately and associations with demographic and clinical characteristics. The prevalence of psychotropic medicines classes will be estimated. Unpaired t-tests and Mann-Whitney and ANOVA tests will be used to compare the two cohorts. Binary logistic regression will be performed to estimate odds ratios for “any psychotropic” in Wave 4 participants compared to those at Wave 1, adjusting for confounders. Patterns of psychiatric healthcare utilisation and availability of easy-to-read medicines information will be compared for those at Wave 1 and those at Wave 4.

Work package 5 – *Ensure patients and key stakeholders are involved in a meaningful and informative manner from inception to dissemination*

IDS-TILDA have well established consultation processes with advocacy groups in several service providers throughout the country. These groups will be invited to contribute to the review of the project goals and establish the knowledge base, in collaboration with the HSE task group. An independent advocate will be included on the project management group. Robust dissemination will be undertaken to ensure all stakeholder needs are met, including the production of an easy read accessible findings report. Dissemination will be conducted via infographics, videos and educational webinars as well as a webpage on the TCAID website which will act as an information hub for the project. Working with the consultation advocacy groups and the HSE task group, the main findings will be produced into easy read formats. The advocacy and focus groups will review the report for clarity, understanding and accessibility. The project will engage in national and international dissemination through peer review publications, position papers, conferences, and invited talks with service providers and advocacy groups. The consultation advocacy groups will also contribute to the identification of priorities for practice emanating from the findings of the project and translation into a meaningful tool to inform, educate and empower the end-user in practice, e.g., development of psychotropic prescribing guidelines that are patient-centred.

Discussion

The aim of this study is to examine the quality and trends of psychotropic use of older adults with intellectual disability over a ten-year period in Ireland to inform practice and policy and optimise medicines use and health outcomes. This

study will add value for the population of older adults with intellectual disability by revealing the following: (i) the effects of psychotropic medicines on cognitive and physical functions, (ii) the change in patterns in psychotropic medicines, (iii) the influence of different factors (e.g., change in place of residence) on psychotropic use patterns, and (iv) the differences in psychotropic prescribing patterns for those age 40–49 years in 2009/2010 and those aged 40–49 years who were newly recruited in Wave 4 in 2019/2020. Finally, the findings will be used by the HSE to influence policy and improve prescribing. The objectives noted above will be achieved through the completion of 4 work packages, outlined in the Methods section.

Work package 1 will add to existing research on the effects of psychotropic medicines. Previous research has investigated medication use in adults with intellectual disability^{1,2,26} however there remains a large knowledge gap in this area which work package 1 will address, specifically in relation to cognitive and physical function.

This work package will also address whether deinstitutionalisation of adults with intellectual disability will have resulted in changes in medications.

Work package 2 will utilise data from both 10-year IDS-TILDA and HSE-PCRS to assess potential changes in medication usage, with particular interest in patterns of psychotropic medicines. Work package 3 compliments work package 2 by examining the influence of change in residence and its impact on psychotropic use. No similar comparative study has been conducted before in Ireland.

Work package 4 will allow for assessment on the trends of medication prescribing in the youngest cohort in Wave 1 and Wave 4 (40–49 years). Similar work has not been conducted before in Ireland.

The findings from the four work packages will then inform the formation of prescribing guidelines on psychotropic medicine use in adults with intellectual disability as well as audit-standards for anti-psychotic medications in this cohort. Results will be comparable with international findings and provide some key opportunities and recommendations for future research. Study findings will be disseminated via publications in peer reviewed journals and presented at relevant conferences. Adults with intellectual disability and other stakeholders will be involved from the beginning of the study up to its conclusion and will be involved in drafting articles, presentations, triangulation of evidence and development of easy read materials in order to empower individuals with intellectual disability with knowledge on medicines, medicine use and medicine management.

Strengths

IDS-TILDA is the leading longitudinal study on ageing among people with an intellectual disability in Ireland and is the first of its kind in Europe. The regularly repeated measures

within the same population at four time points during the ten years period means trends and patterns are tracked for psychotropic medicines use including the influence of different factors on psychotropic medicines use patterns (e.g., change in place of residence). To ensure that research is person-centred, inclusive, provides unique and valuable insights and promotes a sense of ownership and empowerment for participants, people with intellectual disability and their family members/care givers have been involved from the outset in the steering committee. Similarly, the EQUIP study, will establish an inclusive independent steering committee which will advise on the study protocol, provide advice and oversight and review any ethical issues which might arise.

The HSE-PCRS data is highly accurate given this information is necessary for pharmacies to be reimbursed if required and contains all prescription information for that individual⁴. Combining the medication data from IDS-TILDA and the HSE-PCRS will ensure findings are accurate and up to date. This will be the first time there will be such linkage.

Limitations

Participants of IDS-TILDA are asked if they have received a diagnosis of an emotional/nervous or psychiatric condition. IDS-TILDA does not gather information from healthcare professionals notes and as such the diagnosis is therefore self-report, however, IDS-TILDA does allow time for individuals to check diagnosis. The authors also acknowledge that recall bias may have impacted the responses provided

by participants as is the case with all epidemiological retrospective studies.

Data available for analysis is only available for those in wave 4 of IDS-TILDA who consented and provided their PCRS number. As such, we are not able to determine if the findings will be representative of the whole population.

Reporting guidelines

This study will follow the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) standardised reporting guidelines for cohort studies⁶.

Study status

Work package 1 is almost completed and components of work packages 2, 3 and 4 have been completed. A steering group has been formed which correlates with work package 5.

Data availability

No data are associated with this article.

Acknowledgements

The authors would like to acknowledge all participants in IDS-TILDA since its inception as well as the individuals who have supported this work. The authors acknowledge the assistance of the HSE-PCRS for the linkage element of the study. The authors would also like to thank the EQUIP study funders – the HRB – who also fund IDS-TILDA.

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Open Peer Review

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Danielle Adams 

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Thank you for asking me to review this study protocol. The rational and objectives of this proposed study, using a high quality data set from IDS TILDA, is much needed and will add considerable valuable evidence to both the prevalence and the effects of prescribing psychotropic medicines to people with an intellectual disability in Ireland. Its good external validity will affect the impact that the findings will have outside Ireland.

I suggest that the following grammatical issues are looked at by the authors.

- There are some inconsistencies regarding the use of the following terms: "behaviour that challenge" and "behaviours which challenge", "disability" and "disabilities".
- Table 1 second column, second row, "behaviour that challenge" is repeated.
- Page 6 work package 2 second column line 4 ""behaviour that challenge" is repeated.
- Discussion page 8 second column grammar incorrect in the following sentence "Similar work has not been conducted before changes in prescribing trends over a ten-year period."
- Looking forward to seeing the results of this study.

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: Deprescribing psychotropic medicines in people with an intellectual disability

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.
