

# Anti-psychotic drug reduction in primary care for adults with learning disabilities

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|----------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>25/03/2013   | <b>Recruitment status</b><br>No longer recruiting             | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>08/04/2013 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>06/08/2018       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

### Background and study aims

About 1 in 200 adults are recognised as having a learning disability. Illness in this population is high, including significant rates of challenging behaviour and mental illness. Use of psychoactive medication is high and there is particular concern over the use of anti-psychotic medication that is prescribed for reasons other than the treatment of psychosis. Control of challenging behaviour is the primary reason why such medications are prescribed despite the absence of good evidence for any therapeutic effect for this purpose. This problem is central to the intervention being evaluated in this study.

### Who can participate?

Patients aged 18 and over and their carers from across South Wales and various locations in England from learning disabilities registers

### What does the study involve?

Participants are randomly allocated to the intervention group or the control group. Participants meet with the research team five times over the course of 12 months to complete assessments. During the study, those in the intervention group proceed through four monthly approximately 25% reduction stages within a 6-month period (although blinded, the GP has discretion to delay progression to the next step). The control group maintain baseline treatment. Treatment achieved at 6 months is maintained for a further 3 months under blind conditions. At 9 months, the blinding is broken for clinicians and participants and medication changes monitored over the 12-month period.

### What are the possible benefits and risks of participating?

Taking part in the study may not necessarily bring about immediate benefits but the information gained will help treat people who will take either Haloperidol or Risperidone in the future. The main risk is that the patient might start to feel worse if their study medication is reduced. GPs receive support in order to know how best to handle any such situations.

### Where is the study run from?

The South East Wales Trials Unit at Cardiff University (UK)

When is the study starting and how long is it expected to run for?

April 2013 to June 2016

Who is funding the study?

National Institute for Health Research Health Technology Assessment Programme (UK)

Who is the main contact?

Prof. Michael Kerr

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2013-000389-12

### Protocol serial number

HTA 10/104/20, SPON 1173-12

## Study information

### Scientific Title

ANDREA-LD: ANti-psychotic Drug REduction in primary care for Adults with Learning Disabilities (ANDREA-LD): a randomised double-blind placebo-controlled trial

### Acronym

ANDREA-LD

### Study objectives

To evaluate the impact of a blinded anti-psychotic medication withdrawal programme for adults with learning disabilities (LD) without psychosis compared to treatment as usual.

### Ethics approval required

Old ethics approval format

## **Ethics approval(s)**

Research Ethics Committee for Wales, 04/04/2013, ref: 13/WA/0034

## **Study design**

Randomised double-blind placebo-controlled non-inferiority withdrawal trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Learning disabilities

## **Interventions**

Participants will be taking either risperidone or haloperidol at the start of the study. They will then be randomised to either the dose reduction arm or the treatment as normal arm. Those in the dose reduction arm will have their original (baseline) level of risperidone or haloperidol reduced in 4 (approximately 25%) reduction stages. This is a double blinded study so all study medication will be encapsulated. For those undergoing the reduction, a placebo will also be introduced in order to maintain the number of pills being administered. The control group will maintain baseline treatment. Treatment achieved at 6 months will be maintained for a further 3 months under blind conditions. At this point the blind is broken for the final 3 months of the study in order to monitor prescribing habits.

## **Intervention Type**

Drug

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Risperidone, haloperidol

## **Primary outcome(s)**

Aggression, evaluated using the Modified Overt Aggression Scale (MOAS). The MOAS rates four categories of aggression (verbal aggression, destruction of property, self-mutilation and physical aggression to others) measured at baseline, 6 months, 9 months and 12 months.

## **Key secondary outcome(s))**

1. Adaptive behaviour, measured using the Adaptive Behaviour Scale (ABS) at screening
2. Mental health, measured using the Psychiatric Assessment Schedule for Adults with Developmental Disability Checklist (PAS-ADD) at screening, baseline, 6 months, 9 months and 12 months
3. Adverse effects of psychotropic medication, measured using the Udvalg for Kliniske Undersøgelser scale (UKU) at baseline and 9 months
4. Movement disorders, measured using the Dyskinesia Identification System Condensed User Scale (DISCUS) at baseline and 9 months

5. Other challenging behaviour, measured using the Aberrant Behaviour Checklist (ABC) at baseline, 6 months, 9 months and 12 months
6. Costs, measured using the Client Service Receipt Inventory [modified] (CSRI) at baseline, 6 months, 9 months and 12 months

**Completion date**

30/06/2016

## Eligibility

**Key inclusion criteria**

1. Aged 18 or over
2. Have a learning disability as judged by administrative classification (e.g. on practice learning disability register, in receipt of an annual learning disability health check, in receipt of learning disability services) and a score on the Adaptive Behaviour Scale that converts to an estimated IQ of 70 or below using the method described by Moss and Hogg
3. Currently prescribed one of two anti-psychotic drugs, haloperidol or risperidone, for treatment of challenging behaviour

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Current diagnosis of psychosis
2. Known recurrence of psychosis following previous drug reduction in the past 3 years
3. The clinician responsible for their treatment judges for any other reason that the participation in a drug reduction programme may be counter-indicated.

**Date of first enrolment**

01/11/2013

**Date of final enrolment**

01/02/2015

## Locations

**Countries of recruitment**

United Kingdom

Wales

**Study participating centre**

**Cardiff University**

Cardiff

United Kingdom

CF14 4YS

## Sponsor information

**Organisation**

Cardiff University (UK)

**ROR**

<https://ror.org/03kk7td41>

## Funder(s)

**Funder type**

Government

**Funder Name**

Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

| Output type                          | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>      | results | 01/08/2017   |            | Yes            | No              |
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |