Appendix 1: The Standard Protocol Items: Recommendations for Interventional trials (SPIRIT checklist)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym ✓ Title Page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry ✓ Pg 2; Abstract ; trial registration
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier ✓ Pg 2; abstract; trial registration
Funding	4	Sources and types of financial, material, and other support ✓Pg 10
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors ✓ Title page
	5b	Name and contact information for the trial sponsor ✓Title page
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities ✓ Pg10
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) ✓ Pg 8
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention ✓ Pg 3; intro
	6b	Explanation for choice of comparators ✓ Pg 3; intro
Objectives	7	Specific objectives or hypotheses ✓ Pg 3; aims
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) ✓ Pg 3; study setting & design

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained ✓ Pg 3; study setting & design
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) ✓ Pg 3-4
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered ✓ Pg 5; intervention
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) ✓ Pg 6; step 5
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) ✓ Pg 6; steps 4 & 5
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial ✓ Pg 6; step 4; line 21-22
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended ✓ Page 8; outcomes
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) ✓ Pg 5; intervention
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations Pg 9; power & sample size ✓
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size ✓ Pg 9; power & sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions N/A

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions N/A
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial N/A
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol ✓ Pg 7; Data collection
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols ✓ Pg 9; lines 22-25
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol ✓ Pg 7; Data collection
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol ✓ Pg 9; statistical methods & analysis
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) ✓ Pg 9; statistical methods & analysis; Figure 1
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) ✓ Pg 9; statistical methods & analysis
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed ✓ Pg 8; paragraph 1

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial ✓ Pg 8; data monitoring & safety
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct ✓ Pg 7; lines 6-9
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor ✓ Pg 8; data monitoring & safety

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval ✓ Pg 9; ethics & disemmination
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) ✓ Pg 9; ethics & disemmination
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) ✓ Pg 4
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial Appendices 2 & 3
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site ✓ Pg 10
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators ✓ Pg 9; ethics & disemmination
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions ✓ Pg 9; ethics & disemmination
	31b	Authorship eligibility guidelines and any intended use of professional writers N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code ✓ Pg 9; ethics & disemmination

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	✓ Appendices 2 & 3
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Appendix 2: Patient information and consent forms for participants

Participant Information Sheet

Study title: Deprescribing anticholinergic and sedative medicines: A Feasibility study (DEFEAT-study) in residential aged care facilities

Locality: Timaru, NZ	Ethics committee ref.:
Lead investigator: Nagham Ailabouni	Contact phone number: 021-1226416

You are invited to take part in a study about Deprescribing. Deprescribing is the process of reducing and/or discontinuing medicines that may be inappropriate, harmful or no longer necessary. Whether or not you take part is your choice. If you do not wish to take part, you don't have to give a reason, and it won't affect the care you receive. If you wish to take part now, but change your mind later, you can withdraw from the study at any time.

This participant information sheet will help you decide if you wish to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. We expect this will take approximately 20 minutes. You may also want discuss the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 6 pages long, including the Consent Form. Please make sure that you have read all the pages.

Why are we doing the study?

Residents living in residential care aged care facilities are sometimes prescribed medicines they no longer need. The more medicines you take, the more susceptible you are to experiencing one or more negative health effects. These can include, for example, falling or experiencing uncomfortable drug side effects. Side effects can include having blurred vision, dry mouth, constipation or experiencing constant muscle pain or nightmares.

In particular, sedative and anticholinergic medicines, such as sleeping tablets or antidepressants tend to be overprescribed to older people. Side effects such as confusion, dizziness, poor quality of sleep and an increased number of falls have been reported with use of these medicines. This study aims to investigate whether it is feasible to reduce or discontinue these medicines and whether this will improve your quality of life and wellbeing.

In this study, a New Zealand registered pharmacist and PhD candidate from the University of Otago, Mrs. Nagham Ailabouni, will work alongside you and your general practitioner (GP) to review all medicines you are currently taking, in an attempt to discontinue or reduce anticholinergic and sedative medicines.

The study is being carried out by the following researchers:

- Dr Prasad Nishtala, Senior Lecturer, School of Pharmacy, University of Otago
- Professor Dee Mangin, Professor, University of Otago, Christchurch and David Braley Nancy Gordon, Chair in Family Medicine, McMaster University, Canada
- Nagham Ailabouni, PhD Candidate, School of Pharmacy, University of Otago

Nagham Ailabouni is conducting this study as the basis for the degree of Doctor of Philosophy at The University of Otago. This will take place under the supervision of Dr. Prasad Nishtala and Professor Dee Mangin.

This study is funded by an independent organization, the New Zealand Lotteries Health Research. Ethics approval to carry out this study has been granted, by the Human and Disability Human Ethics committee on this date xx/xx/xx (TBC).

If you have any questions regarding this project, you may contact the Principal investigator, Nagham Ailabouni, or any of the other principal researchers involved. Their details are listed on the page 7 of this document.

What would your participation involve?

If you choose to participate in this study, you will be asked to read this information sheet carefully and sign the consent form on page 8 of this document. In total, you will be asked to attend four main appointments with the pharmacist over a period of six months. You may wish to invite any of your relatives, family or whānau to this appointment and all future appointments. These appointments will include:

1) Initial appointment

Prior to this appointment, the pharmacist will thoroughly read your clinical notes and assess your medicine chart. With the help of the nurse, the pharmacist will schedule an appointment at a time that is convenient to you. At this appointment, the pharmacist will have an in-depth discussion with you about your current beliefs and ideas regarding your medicines, and any concerns you may have about any of your prescribed medicines. The purpose of this discussion is to ascertain any medicine(s) that you may be having trouble taking or would not like to continue taking.

In addition to this, the pharmacist will ask you, with the help of your chosen relative or friend to complete a survey. The survey will include a number of questions, for example, it will help to assess your current quality of life, and the appropriateness of all your medicines. The pharmacist will record this information alongside information from your medical notes in a secure and password protected computer database. This information will be de-identified and will be securely stored in such a way that only the principal researchers whose details are available on page 7, can

access it. The data monitoring committee of the study, consisting of another pharmacist and a biostatistician will also have access to this de-identified data in order for them to monitor the validity of the study data and the overall safety of the study.

The pharmacist will document the discussion that took place at this initial appointment in a purposive developed study document. You and your relative or family member will be provided with a hard copy of this document. If you are unhappy with any of the document's content, you have the right to request the pharmacist to change this.

2) Multi-disciplinary clinical review meeting

The pharmacist will submit recommendations to your GP based on the scientific evidence to reduce or discontinue the anticholinergic or sedative medicines that you may be prescribed. The pharmacist and your GP will discuss these recommendations. A meeting may be thought to be helpful to plan for you, and if so, you will be invited to attend this meeting with your chosen friend or relative. The registered nurse and general practitioner who are involved with your care, along with the pharmacist, will also be present at this meeting.

The recommendations that the pharmacist has made to your GP will be discussed. At any point, you have the freedom to refuse any of the recommendations that have been put forward.

An appropriate medication management plan (MMP) to reduce these medicines in a way that is safe and appropriate will be formulated. Certain monitoring might need to take place to ensure that you are healthy and fit. Standard blood tests will be ordered by your GP for monitoring.

After a medicine is reduced or discontinued, the pharmacist will follow up with you and review your wellbeing, twice a week. After two weeks, if you are stable and doing well, the dose will be further reduced or the next target medicine will be reduced. This process will continue until all target medicines are withdrawn and you are deemed to be stable. The pharmacist will then follow up with you, weekly for a further two visits and, if stable, no additional visits, besides those outlined above, will be conducted.

3) Three month appointment

At three months, the pharmacist will review all of your current medical information. The pharmacist will ask you about any medication side effects, in the presence of your relative or family member. This will be carried out in order to ascertain any changes to your health that could have resulted after reducing or discontinuing one or more of the medicines that you had been taking.

4) Six month appointment

At six months, the pharmacist will recollect all of your current medical information. She will carry out the same tests outlined above in the presence of your relative or family member. This will be carried out in order to ascertain any changes to your health that could have resulted after reducing or discontinuing one or more of the medicines you had been taking.

What are the possible benefits and risks to you of participating?

If you decide to participate in this study, you may experience one or more possible health benefits. You may feel better overall as you will have a reduced risk of suffering from the harmful effects your medicines. These include symptoms such as a dry mouth, blurred vision, confusion, agitation and even nightmares. You also may feel more mobile and active.

On the other hand, you may not experience any benefits from stopping any of your medicines. When reducing or stopping anticholinergic and sedative medicines (defined above), some patients may be susceptible to developing adverse drug withdrawal effects (ADWEs). ADWEs occur

because your body may have become used to the medicines after being prescribed them for a long period of time. To prevent ADWEs and reduce your risk of developing them, all target medicines will be slowly reduced or discontinued. In addition, you will be thoroughly monitored by the pharmacist and nursing staff. If any unexpected adverse effect is noted, or if you report to us that you are not feeling well, your GP will be immediately contacted for prompt medical attention.

The reason to why you have been feeling unwell will be ascertained, and explained to you. We will inform you that if the reason is likely to be as a result of reducing or discontinuing your medicines. If this is the case, you will be reminded of your option to withdraw from the study with no disadvantage being made to yourself. No payment or reimbursement will be provided for participants in this study.

What would happen if you were injured in the study?

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover. If you were injured in this study, which is unlikely, you would be eligible for compensation from Accident Compensation Corporation (ACC) just as you would be if you were injured in an accident at work or at home.

What are the rights of participants in the study?

If you decide to participate in the study, you will be assigned a specific study ID number. This will prevent your personal name being linked to any information that will be collected. All of the collected health information will be securely stored in a password-protected file, on a password-protected computer. This information will be backed up on a secure University of Otago network. Members of the research team (listed on page 6) are the only individuals who may access this information, during the course of the study.

Participation in this study is not obligatory. We expect that you might benefit from participating, however it is completely up to you whether you accept to participate or decline. You are also free to seek advice from your family member(s), relatives or friends about participating in this study. If you decide to participate in this study, you have the right to withdraw from the study and decline continuing to participate at any stage. You do not have to provide a full reason for why you do not wish to continue. However, this information would be very helpful and useful to the study.

During the outlined appointments or follow-ups the pharmacist will conduct during the study, you will be informed of any marked improvements to your health that could be attributed to your medicines being reduced or discontinued. You and your family member(s) or relative will also receive a copy of all formal documentation that may arise from meetings during the study. The pharmacist will explain these documents to you as necessary and you may ask her any questions you may have regarding these documents or the study. You have the right to request your health information to be deleted or altered. The pharmacist will amend your health information records according to your feedback, as appropriate.

As explained above, if you were to suffer from a harmful effect that is thought to be linked to stopping or reducing your medicines, the pharmacist or the GP will inform you of this. At this point, you will be reminded of your right to withdraw participation from the study. If you wish to withdraw, no disadvantage will be made to you as a result. You will continue to receive your usual medical care by your GP and nursing staff.

What will happen after the study ends, or if you pull out?

No study intervention will occur after the conclusion of the study. Health information (i.e. study data) collected will be securely stored in such a way that only those researchers mentioned below will be able to gain access to it. At the end of the project, any personal information will be destroyed immediately except that any raw data on which the results depend will be retained in secure storage for ten years after which it will be destroyed.

Any reports about this project will contain information that is amalgamated for all the participants as a group, so it will not be possible to identify any individual in any of these reports. You are welcome to request a copy of the results of the project from the investigators.

The results of the project may be published in a peer-reviewed scientific journal. This may occur one to two years after the completion of the study. The publication will be emailed to the managers of the residential care aged facility. You may request for it to be emailed to yourself or designated family member(s) or relative.

Where can you go for more information about the study, or to raise concerns or complaints?

If you have any question or concerns about the study at any stage, you can contact:

Mrs Nagham Ailabouni
PhD candidate
School of Pharmacy
University of Otago
PO Box 56, Dunedin 9054
New Zealand
(03) 479 7321
nagham.ailabouni@otago.ac.nz

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PO Box 56, Dunedin 9054
New Zealand
(03) 479 4041
prasad.nishtala@otago.ac.nz

Professor Derelie Mangin*
Co-supervisor
Dept of General Practice,
University of Otago, Christchurch
David Braley
Chair in Family Medicine
McMaster University
Canada
mangind@mcmaster.ca

*School of Medicine, University of Otago, Christchurch

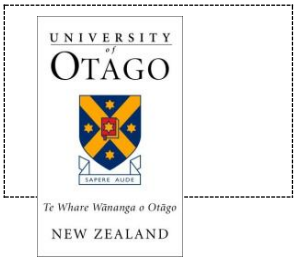
This information sheet is for you to keep. If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@hdc.org.nz

If you are concerned about the way this study is being conducted or you wish to make a formal compliant. Please contact the health and disability ethics committee (HDEC) that approved this study. Please quote the study title and protocol number.

Phone: xx xxx xxxx Email: xxx@moh.govt.nz

Consent Form



Declaration by participant:

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet. I have had the opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this study.

I have been given a copy of the Participant Information Sheet and Consent Form to keep.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date:

Appendix 3: Patient information and declaration form for participants' enduring power of attorney (EPOA)

Participant Information Sheet

Study title: Deprescribing anticholinergic and sedative medicines: A Feasibility study (DEFEAT-study) in residential aged care facilities

Locality:
Timaru, NZ

Ethics committee ref.:

Lead investigator:
Nagham Ailabouni

Contact phone number: 021-1226416

Your relative/donor is invited to take part in a study about Deprescribing. Deprescribing is the process of reducing and/or discontinuing medicines that may be inappropriate, harmful or no longer necessary. Whether or not your relative/donor takes part is your choice. If you do not wish for them to take part, you don't have to provide a reason, and it won't affect the care that they receive. If you decide they may take part in the study, but change your mind later, you can withdraw your relative/donor from the study at any time.

This participant information sheet will help you decide if you wish for the relative/donor to take part. It sets out why we are doing the study, what their participation would involve, what the benefits and risks to them might be, and what would happen after the study ends. You may also want discuss the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree for your relative/donor to take part in this study, you will be asked to sign the declaration Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the declaration Form to keep.

This document is 6 pages long, including the declaration Form. Please make sure that you have read all the pages.

Why are we doing the study?

Residents living in residential care aged care facilities are sometimes prescribed medicines they no longer need. The more medicines they take, the more susceptible they are to one or more negative health effects. These can include, for example, falling or experiencing uncomfortable drug side effects. Side effects can include having blurred vision, dry mouth, constipation or experiencing constant muscle pain or nightmares.

In particular, sedative and anticholinergic medicines, such as sleeping tablets or antidepressants tend to be overprescribed to older people. Side effects such as confusion, dizziness, poor quality of sleep and an increased number of falls have been reported with use of these medicines. This study aims to investigate whether it is feasible to reduce or discontinue these medicines and whether this will improve your relative/donor's quality of life and wellbeing.

In this study, a New Zealand registered pharmacist and PhD candidate from the University of Otago, Mrs. Nagham Ailabouni, will work alongside you and your general practitioner (GP) to review all medicines you are currently taking, in an attempt to discontinue or reduce anticholinergic and sedative medicines.

The study is being carried out by the following researchers:

- Dr Prasad Nishtala, Senior Lecturer, School of Pharmacy, University of Otago
- Professor Dee Mangin, Professor, University of Otago, Christchurch and David Braley Nancy Gordon, Chair in Family Medicine, McMaster University, Canada
- Nagham Ailabouni, PhD Candidate, School of Pharmacy, University of Otago

Nagham Ailabouni is conducting this study as the basis for the degree of Doctor of Philosophy (PhD) at The University of Otago. This will take place under the supervision of Dr. Prasad Nishtala and Professor Dee Mangin.

This study is funded by an independent organization, the New Zealand Lotteries Health Research. Ethics approval to carry out this study has been granted, by the Human and Disability Human Ethics committee on this date xx/xx/xx (TBC).

If you have any questions regarding this project, you may contact the Principal investigator, Nagham Ailabouni, or any of the other principal researchers involved. Their details are listed on the page 7 of this document.

What would your relative/donor's participation involve?

If you agree for your relative/donor to take part in the study, they will be asked to attend in total four main appointments with the pharmacist over a period of six months. You may wish to invite any of your relatives, family or whānau to this appointment and all future appointments. These appointments will include:

1) Initial appointment

Prior to this appointment, the pharmacist will thoroughly read your relative/donor's clinical notes and assess their medicine chart. With the help of the nurse, the pharmacist will schedule an appointment at a time that is convenient to your relative. You are also welcome to attend this meeting. At this appointment, the pharmacist will have an in-depth discussion with you about your relative/donor's medicines, and discuss any concerns you may have about any of their prescribed medicines. The purpose of this discussion is to ascertain any medicine(s) that you might think your relative/donor doesn't need to continue taking.

In addition to this, the pharmacist will ask your relative/representative, with your help to complete a survey. The survey will include a number of questions to help to assess your relative/donor's current quality of life, and the appropriateness of all their medicines. The pharmacist will record this information alongside information from their medical notes in a secure and password protected computer database. This information will be de-identified and will be securely stored in such a way that only the principal researchers whose details are available on page 7, can access it. The data

monitoring committee of the study, consisting of another pharmacist and a biostatistician will also have access to this de-identified data in order for them to monitor the validity of the study data and the overall safety of the study.

The pharmacist will document the discussion that took place at this initial appointment in a purposive developed study document. You and your relative or family member will be provided with a hard copy of this document. If you are unhappy with any of the document's content, you have the right to request the pharmacist to change this.

2) Multi-disciplinary clinical review meeting

The pharmacist will submit recommendations to your relative/donor's GP based on the scientific evidence to reduce or discontinue the anticholinergic or sedative medicines that your relative/donor may be prescribed. The pharmacist and your GP will discuss these recommendations. A meeting may be thought to be helpful to plan the process for your relative/donor. If so, you will be invited to attend this meeting along with the registered nurse, the pharmacist and the general practitioner who are involved with your relative/donor's care.

The recommendations that the pharmacist has made to your GP will be discussed openly at this meeting. At any point, you have the freedom to refuse any of the recommendations that have been put forward.

An appropriate medication management plan (MMP) to reduce these medicines in a way that is safe and appropriate will be formulated. Certain monitoring might need to take place to ensure that your relative/donor are healthy and fit. Standard blood tests will be ordered by the GP for monitoring.

After a medicine is reduced or discontinued, the pharmacist will follow up with your relative/donor to review their wellbeing, twice a week. After two weeks, if your relative/friend are stable and are doing well, the dose of the medicine will be further reduced or the next target medicine will be reduced. This process will continue until all target medicines are withdrawn and your relative/donor are deemed to be stable.

3) Three month appointment

At three months, the pharmacist will review all of your relative/donor's current medical information. The pharmacist will carry out the same tests outlined above, in your presence if feasible. This will be carried out in order to ascertain any changes to your relative/donor's health that could have resulted after reducing or discontinuing one or more of the medicines that they had been taking.

4) Six month appointment

At six months, the pharmacist will recollect all of your relative/donor's current medical information. She will carry out the same tests outlined above. This will be carried out in order to ascertain any changes to your health that could have resulted after reducing or discontinuing one or more of the medicines they had been taking.

What are the possible benefits and risks to your relative/donor of participating?

If you agree for your relative/donor to participate in this study, they may experience one or more possible health benefits. They may feel better overall as they will have a reduced risk of suffering from the harmful effects caused by some of their medicines. They may also feel more mobile and active.

On the other hand, your relative/donor may not experience any benefits from stopping any of their medicines. When reducing or stopping anticholinergic and sedative medicines (defined above), some patients may be susceptible to developing adverse drug withdrawal effects (ADWEs). ADWEs occur because your body may have become used to the medicines after being prescribed them for a long period of time.

To prevent ADWEs and reduce your risk of developing them, all target medicines will be slowly reduced or discontinued. In addition, your relative/donor will be thoroughly monitored by the pharmacist and nursing staff. If any unexpected adverse effect is noted, their GP will be immediately contacted for prompt medical attention.

The reason to why your relative/donor may have been feeling unwell will be ascertained, and explained to them and yourself. We will inform you if the reason is likely to be as a result of reducing or discontinuing their medicines. If this is the case, you will be reminded of your option to withdraw your relative/friend from the study with no disadvantage being made to them or yourself. No payment or reimbursement will be provided for participants in this study.

What would happen if your relative/donor were injured in the study?

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover. If you were injured in this study, which is unlikely, you would be eligible for compensation from Accident Compensation Corporation (ACC) just as you would be if you were injured in an accident at work or at home.

What are the rights of participants in the study?

Your relative/donor will be assigned a specific study ID number. This will prevent their personal name being linked to any information that will be collected. All of the collected health information will be securely stored in a password-protected file, on a password-protected computer. This information will be backed up on a secure University of Otago network. Members of the research team (listed on page 6) are the only individuals who may access this information, during the course of the study.

Participation in this study is not obligatory. We expect that your relative/donor might benefit from participating, however it is completely up to you whether you accept for them to participate or decline this request.

You are also free to seek advice from your family member(s), relatives or friends about your relative/donor participating in this study. If you decide for your relative/donor to participate in this study, you have the right to withdraw from the study and decline continuing to participate at any stage. You do not have to provide a full reason for why you do not wish for your relative/donor to continue to participate in the study. However, this information would be very helpful and useful to the study.

During the outlined appointments or follow-ups the pharmacist will conduct during the study, you will be informed of any marked improvements to your health that could be attributed to your medicines being reduced or discontinued. You and your relative/donor will also receive a copy of all formal documentation that may arise from meetings during the study. The pharmacist will explain these documents to you as necessary and you may ask her any questions you may have regarding these documents or the study. You have the right to request your relative/donor's health information to be deleted or altered. The pharmacist will amend your health information records according to your feedback, as appropriate.

As explained above, if your relative/donor were to suffer from a harmful effect that is thought to be linked to stopping or reducing your medicines, the pharmacist or the GP will inform you of this. At this point, you will be reminded of your right to withdraw your relative/donor from participating in the study. No disadvantage will be made to your relative/donor as a result. They will continue to receive their usual medical care by their GP and nursing staff.

What will happen after the study ends, or if you pull out?

No study intervention will occur after the conclusion of the study. Health information (i.e. study data) collected will be securely stored in such a way that only those researchers mentioned below will be able to gain access to it. At the end of the project, any personal information will be destroyed immediately except that any raw data on which the results depend will be retained in secure storage for ten years after which it will be destroyed.

Any reports about this project will contain information that is amalgamated for all the participants as a group, so it will not be possible to identify any individual in any of these reports. You are welcome to request a copy of the results of the project from the investigators.

The results of the project may be published in a peer-reviewed scientific journal. This may occur one to two years after the completion of the study. The publication will be emailed to the managers of the residential care aged facility. You may request for it to be emailed to yourself or designated family member(s) or relative.

Where can you go for more information about the study, or to raise concerns or complaints?

If you have any question or concerns about the study at any stage, you can contact:

Mrs Nagham Ailabouni
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Professor Derelie Mangin*
Co-supervisor
David Braley Nancy Gordon
Chair in family medicine
McMaster University
Canada
mangind@mcmaster.ca

*School of Medicine, University of Otago, Christchurch

This information sheet is for you to keep. If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@hdc.org.nz

If you are concerned about the way this study is being conducted or you wish to make a formal compliant. Please contact the health and disability ethics committee (HDEC) that approved this study. Please quote the study title and protocol number.

Phone: xx xxx xxxx Email: xxx@moh.govt.nz

Declaration Form

Declaration by enduring power of attorney (EPOA), on behalf of the participant:

I have read, or have had read to me in my first language, the participant information sheet, and I understand it. I have had the opportunity to ask questions and I am satisfied with the answers I have received.

I have been given a copy of the Participant Information Sheet and Consent Form to keep.

I believe that this study might benefit my relative/donor, and would be in line with his/her interests:

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant's EPOA, and have answered their questions about it.

I believe that the participant's EPOA understands the study and believes that the participation of his/her relative would be in line with their relative's interests.

Researcher's name:

Signature: Date:

Appendix 4: GP participant enrolment form

Deprescribing anticholinergic and sedative medicines: A Feasibility Trial (DEFEAT-study) in residential aged care facilities

Insert Date

Dear Dr X,

Please find below a list of the names of potential participants who are unable to provide their own consent and their EPOA have either agreed for them to take part in the study, or their EPOA have not yet responded.

Please indicate, by ticking the box next to the potential participant's name, if you agree that the deprescribing intervention, proposed in the study, might be beneficial to them. If you disagree for any potential participant to take part in the study, please indicate this in the designated box provided, along with a brief reason as to why the intervention would be unsuitable for them (e.g:. previous unsuccessful attempt at discontinuing medicines, resident receiving palliative care etc.)

Potential participants whose EPOAs have agreed for their resident to take part			**Potential participants whose EPOAs have not responded**		
Name	✓ / X	Reason for disagreeing to enrol participant	Name	✓ / X	Reason for disagreeing to enrol participant

GP signature: _____

Appendix 5: General practitioner invitation letter

Deprescribing anticholinergic and sedative medicines: A Feasibility Trial (DEFEAT-study) in residential aged care facilities

Insert Date

Dear Dr X,

I am writing to inform you of a study that is set to take place this year in three residential care homes in Timaru and Temuka. I would be most grateful if I can organise a fifteen-minute appointment over the next month, in order to discuss and explain the study's protocol in-depth, and address any of your question(s).

This study aims to test a method for reducing polypharmacy. I am a New Zealand (NZ) registered pharmacist and this study is a component of my doctoral studies at the School of Pharmacy, University of Otago. My PhD supervisors are Dr. Prasad Nishtala at the University of Otago, and Professor Dee Mangin from General Practice in Christchurch. The residential age care facilities (RACFs) that will be part of the study are The Croft and Margaret Wilson in Timaru, as well as the Wallingford Complex in Temuka. It is my understanding that you currently provide medical care for one or more of the residents residing in these RACFs. This letter will explain the purpose of the study, the intervention we intend to implement and the health outcomes we hope to achieve.

Deprescribing is the process of safely reducing or discontinuing medicines that are deemed to be inappropriate or no longer necessary. This study will involve deprescribing anticholinergic and sedative medicines, as these medicines are commonly prescribed in older people and are associated with many adverse effects including poor cognitive and physical functioning. Deprescribing has been associated with a lower annual acute hospital admission rate, an improvement in quality of life. No deprescribing studies have been conducted in NZ to indicate whether or not it is feasible.

If one or more of your residents would like to participate in the study, you will be notified of their names and dates of enrolment using your preferred method of contact as soon as possible. After reviewing the participant's medication regimen, drug-specific deprescribing protocols will be utilised to put forward suggestions to you as the participants' general practitioner of drugs that may be suitable to deprescribe (i.e. reduce or discontinue). The details of these recommendations will be summarised in a deprescribing medication review report and this will be emailed to you. Details of the intervention are outlined in-depth in the study protocol, attached to this letter.

We have registered this feasibility study in xxxxx. Testing this method and its effects may benefit you and your patients. It may also provide benefit to others if it proves feasible and successful. Ethical approval for this study has been obtained from the Human & Disability Ethics Committee (HDEC) board.

Yours sincerely,
Nagham Ailabouni, *PhD Candidate, RegPharm NZ, PGCertResPharm (Dist)*
Contact phone number: 021-1226416
Contact email address: Nagham.ailabouni@otago.ac.nz

Appendix 6: Deprescribing drug protocols

Consider reducing if	Consider reviewing & reducing if	Consider resuming if	Consider reviewing & stopping if	Withdrawal effects/ Monitoring
Central Nervous System				
Antipsychotics (APS)				
Patient has dementia and experiences severe neuropsychiatric symptoms (NPS). Studies suggest that worsening of symptoms may occur when discontinuing antipsychotics (APS) in this group of patients [1].	Patient has been prescribed APS for > 3 months & has mild/moderate behavioural and psychological symptoms of dementia (BPSD). APS should be reviewed and tapering of dose should be trialled. Clinical trial evidence has shown no difference to patient's quality adjusted life years (QALY) when APS such as quetiapine, olanzapine & risperidone were discontinued compared to placebo [2]. However, the risk versus benefit of continuing APS's in older people is unfavourable [3] Specific symptom/target behaviour(s) need to be set for all patients initiating or continuing therapy. If the patient has been symptom/target behavior free for at least 3-6 months, then	Withdrawal of APS results in the recurrence/worsening of severe symptoms (e.g.: hallucinations, fixed delusions). Non-pharmacological options have failed and the patient is a threat to self or others [5].	- Prescribed for non-psychotic indications, unless patient is a threat to self or others [5, 6]. - There is no demonstrated benefit or there are un-due side effects [4]. - Reduce dose gradually (e.g. by 50% every two weeks or longer according to patient's response. Stop after the patient is stable on the minimum dose)	- Evidence suggests that the majority of older people with dementia can be withdrawn from long-term APS with no detrimental effects on their behaviour [1]. - Monitor recurrence or emergence of new target symptoms for several months after reducing/discontinuing APS as symptoms might relapse even after a longer period of time [1].

	APS withdrawal should be considered [4].			

Antidepressants

Discontinuation of antidepressants:

1. If a patient is prescribed an antidepressant for a ≥ 6 weeks, this should be reduced gradually over at least four weeks or longer if withdrawal symptoms emerge [7]. There is less evidence for continuing antidepressant treatment in older people for a period ≥ 12 months [8, 9]
2. Rapid discontinuation may result in antidepressant discontinuation syndrome. This is associated with **F**lu-like symptoms, **I**nsomnia, **N**ausea, **I**mbalance, **S**ensory disturbances and **H**yperarousal (anxiety/agitation) (i.e.: FINISH). These usually appear a week after abrupt discontinuation of the antidepressant [10].
3. For patients with more severe symptoms, the original medicine dose may need to be restarted which results in the resolution of symptoms within 24 hours. Tapering can then be reinstated at a slower rate[11].
4. Patients should be monitored carefully as a high risk of suicide attempts exists during dosage changes and discontinuation[12].
5. **Antidepressants and dementia:**
   - Evidence suggests that antidepressants may not be effective for treating depression in dementia [13].
   - The use of antidepressants with anticholinergic properties may exacerbate cognitive decline [14].
   - When discontinuing antidepressants in those who have dementia, the Cornell scale of depression can help to determine the severity of depressive symptoms in these patients. Attaining a similar score to that attained while the patients were on the antidepressants indicates good tolerability to discontinuing therapy[15].

Consider continuing if	Consider reviewing & reducing if	Consider resuming if	Consider reviewing & stopping if	Withdrawal effects Monitoring

Tricyclic Antidepressants (TCAs)				
Patient has been suffering from moderate/severe depressive symptoms and antidepressants have been prescribed for < six months [16, 17]	Deemed necessary to be prescribed, reduce dose to <100mg per day[18].	Patient is suffering from worsening depressive syndromes or showing signs of potential suicidality [12].	Patient has: ➢ Dementia; as there is a risk of worsening cognitive impairment [14]. ➢ Cardiac conduction abnormalities (e.g: pro-arrhythmic effects)[19] ➢ ALT levels three times greater than the upper limit of normal, or has high bilirubin levels or experiences other signs/symptoms of hepatotoxicity [20] ➢ Prostatism or history of urinary retention [21].	➢ Should be withdrawn slowly (e.g: by 25% every four weeks) [10] ➢ Antidepressant discontinuation syndrome (explained above) [7] ➢ Depressive symptoms may re-occur
Selective Serotonin Reuptake Inhibitors (SSRIs)				

Patient has been suffering from moderate/severe depressive symptoms for a period lasting at least three months		Patient is suffering from worsening depressive syndromes or showing signs of suicidality [12]	➢ Co-prescribed with a non-steroidal anti-inflammatory drug (NSAID) or an antiplatelet drug due to an increased risk of upper gastrointestinal (GI) bleeding [22] ➢ Patient has any of the following factors, as they are at a high risk of developing hyponatremia [23]: - > 65 years, female - Low body weight - Concurrent use of medicines that contribute to hyponatremia (e.g.: thiazides, carbamazepine) - Prescribed fluoxetine as an SSRI [24] - Previous history of antidepressant-induced hyponatremia.	- Taper slowly (by 25%) every four to six weeks for medicines with a shorter half-life. Fluoxetine at low doses can be stopped abruptly and does not have to be tapered down, as it has a long half-life [10] - Mild self-limiting symptoms (listed above) could occur within a few days[11]. - These are more common with short-acting antidepressants such as paroxetine and immediate release venlafaxine[11]. - Could be a delay in the presentation of symptoms when fluoxetine is discontinued due to its longer half-life[11]. - Switching patients prescribed paroxetine or venlafaxine to fluoxetine, can decrease the severity of withdrawal symptoms. [25]

Consider continuing if	**Consider reviewing & reducing if**	**Consider resuming if**	**Consider reviewing & stopping if**	**Withdrawal effects**
Benzodiazepines (BZDs)/Non-benzodiazepines (Non-BZDs)				

	- Any high dose of BZD or non-BZDs (such as zopiclone) is prescribed. [5], as the risk of harm is dose-related. Although non-BZDs have been thought to be safer than BZDs, they have similar adverse effect profiles in older people[26]. A recent study showed that older men prescribed non-BZDs are more likely to have a fall than those prescribed a BZD[27]. - The patient has been prescribed the BZD or BZD-agonist for a period longer than 1-4 weeks, as the cumulative use of benzodiazepines for a few weeks has been shown to result in a greater risk of falls and developing withdrawal upon stopping [5, 28-30].		- Any BZD is prescribed as the risk of harm with BZD's has been found to be independent of the medicine's half-life [5]. - Patient experiences recurrent falls or has a history of a previous fracture. The highest risk for falls and fractures exists for older people who have recently been prescribed a high dose of BZD or non-BZD [31, 32].	Need to be withdrawn over a minimum period of 6 months in patients who have been treated long-term. - This reduces the chances of the patient experiencing "BZD withdrawal syndrome", characterised by insomnia, weight loss, sweating, tinnitus (ringing in the ears) and disturbances of perception [33]. - Appearance of this condition can vary from one day after stopping a short-acting BZD, up to three weeks after stopping a long-acting BZD. - Alternative methods to treating insomnia might need to be implemented such as sleep compression (reducing sleep hours to a fixed inadequate period each night, then gradually increasing the number of hours)[10]. - A suggested withdrawal protocol, which could take from 4 weeks up to one year, is as follows [33]: 1) Transfer the patient to the equivalent daily dose of diazepam (preferably taken at night). Equivalent doses for diazepam are listed in the New Zealand Formulary (NZF). 2) Reduce the diazepam dose every 2-3 weeks. If withdrawal symptoms start to appear, maintain the dose until symptoms start to improve. 3) Reduce the dose further, in smaller stops if necessary then stop completely.

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Appendix 7: Deprescribing medication use review form

Deprescribing anticholinergic and sedative medicines: A Feasibility Trial (DEFEAT-study) in residential aged care facilities

Deprescribing Medication Use Review Form

Date: xx/xx/xx

Study ID number: xxxxx
Full name: Mrs./Mr. X
NHI No: XXX123
GP: Dr. X

Your resident has consented to take part in a deprescribing feasibility study. I, Nagham Ailabouni, a New Zealand registered pharmacist and PhD candidate have conducted a deprescribing medication review, after completing an extensive clinical and medical history and having a discussion with the resident regarding their medicines.

The table below provides a summary of the potential medicines that would be appropriate for deprescribing. Please tick the relevant box to indicate whether or not you agree to the discontinuation (i.e. reducing or stopping) of these medicines. If you disagree to initiate discontinuation for any of these medicines in this patient, please state the reason in the far right column.

Medicines appropriate for deprescribing	Reasons for deprescribing	I, as the participant's GP		
		Agree	Disagree	Reasons for disagreeing to initiate discontinuation
1.				
2.				

GP signature: _____

Thank you for completing the table above. I will formulate a medicine management plan (MMP) for this resident within two weeks of receiving this form. This will guide deprescribing for this resident and will ensure deprescribing occurs in a safe manner. The MMP will only include those medicines you have agreed to deprescribe. A copy of this MMP will be emailed to you for approval, prior to providing a copy to the residential care staff or the resident.

Best wishes,

Nagham Ailabouni

PhD Candidate, RegPharm NZ, PGCertResPharm (Dist)
Appendix 8: Medication management plan (MMP) form

Deprescribing anticholinergic and sedative medicines: A Feasibility Trial (DEFEAT-study) in residential aged care facilities

Medication Management Plan

Date: xx/xx/xx

Study ID number: xxxxx
Full name: Mrs./Mr. X
NHI No: XXX123
GP: Dr. X

Mrs./Mr. X's GP has agreed to deprescribe some of Mrs./Mr. X's medicines. The recommended order in which the medicines are to be deprescribed accompanied by appropriate reasoning for deprescribing, is included in the table below.

Medicines	Reasoning for deprescribing	Deprescribing (reducing/stopping) instructions
1.		
2.		
3.		

When anticholinergic and/or sedative medicines are reduced or discontinued, adverse drug withdrawal effects (ADWEs) may develop in some participants. Therefore, it is important to slowly taper the dose of the medicine(s), and monitor the participants closely. We appreciate your help in monitoring the participants.

The following chart is a guide to what you can do, if you note that the resident is experiencing ADWEs.

These ADWEs require **immediate medical attention.**

If the resident develops any of these symptoms, please contact NA immediately (Ph: 021-1226416) and the resident's GP as soon as possible.

- Significantly increased aggressive behaviour
- Significantly increased anxiety
- Harm to one self or another resident/staff member
- Delirium
- Flushing
- Hand tremor
- Seizures
- Increased heart rate or blood pressure

These ADWEs **do not require immediate medical attention.**

If the resident develops any of these symptoms, please note them in the designated section below and notify NA (Ph: 021-1226416) or the resident's GP at the next GP visit.

- Unstable mood patterns
- Diminished appetite or weight loss
- Increased sleep disturbance

These ADWEs **do not require immediate medical attention.**

If the resident develops any of these symptoms, please note them in the designated section below and notify NA (Ph: 021-1226416) and the resident's GP at the next GP visit.

- Change in bowel motions
- Increased headaches
- Blurry vision
- Dry mouth

(Next page)

Notes:

_____

_____

_____

_____

_____

_____

Thank you for your valued cooperation and for monitoring the participants. If you would like to discuss any aspects of this study, please do not hesitate to contact any of the principal investigators whose details are listed below.

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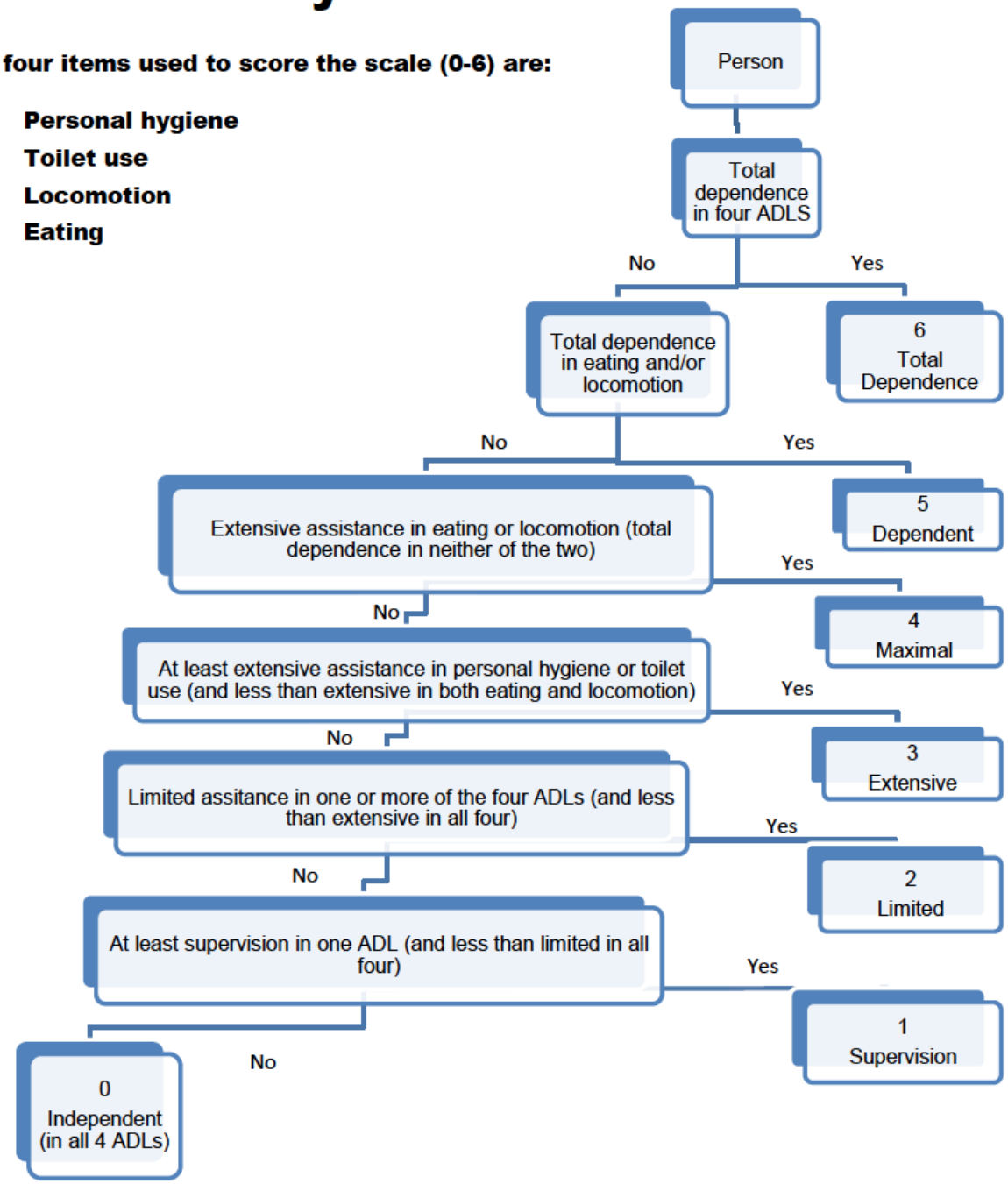
University of Otago, Christchurch.
David Braley Nancy Gordon
Chair in family medicine
McMaster University
Canada
mangind@mcmaster.ca

Appendix 9: Long Term Care Facilities (LTCF) InterRAI scales

ADL Hierarchy Scale

The four items used to score the scale (0-6) are:

- **Personal hygiene**
- **Toilet use**
- **Locomotion**
- **Eating**



Source: Morris JN, Fries BE, Morris SA. (1999) Scaling ADLs within the MDS. Journals of Gerontology: Medical Sciences 54(11):M546-M553.

Updated 9/2014

IADL Performance Scale

Score	IADLS
0–6	Meal preparation
0–6	Ordinary housework
0–6	Managing finances
0–6	Managing medications
0–6	Phone use
0–6	Stairs
0–6	Shopping
0–6	Transportation

Range: 0–48

Scoring in self-performance:

0 = Independent — No help, setup, or supervision

1 = Setup help only

2 = Supervision — Oversight/cuing

3 = Limited assistance — Help on some occasions

4 = Extensive assistance — Help throughout task, but performs 50% of task on own

5 = Maximal assistance — Help throughout task, but performs less than 50% of task on own

6 = Total dependence — Full performance by others during entire period

8 = Activity did not occur during entire period, Score = 6

Depression Rating Scale (DRS)

Score	Item
0-3	Made negative statements
0-3	Persistent anger with self or others
0-3	Expressions (including non-verbal) of what appear to be unrealistic fears
0-3	Repetitive health complaints
0-3	Repetitive anxious complaints/concerns (non-health related)
0-3	Sad, pained, worried facial expression
0-3	Crying, tearfulness

Range: 0-14

Scoring:

0 = No mood symptoms

14 = All mood symptoms present in last 3 days

Scores of 3 or greater indicate major or minor depressive disorders.

The Depression Rating Scale (DRS) is calculated by summing all seven input items after recoding each input item to a three-point (0, 1, 2) scale. For each input item, above, the first two levels, 0 and 1, are not recoded; level 2 is recoded to 1; and level 3 is recoded to 2.

Source: Burrows A, Morris JN, Simon S, Hirdes JP, Phillips C. (2000) Development of a Minimum Data Set-based Depression Rating Scale for Use in Nursing Homes. Age and Ageing 29(2): 165-172.

Changes in Health, End-Stage Disease, Signs, and Symptoms Scale (CHESS)

Score	Item
0–2, 8	Change in decision making
0–3	Change in ADL status
0–2, 8	Change in ADL status
0–4	Health condition — vomiting
0–4	Health condition — peripheral edema
0–3	Health condition — dyspnea
0,1	End-stage disease
0,1	Weight loss
0,1	Insufficient fluid
0,1	Dehydrated
0,1	Decrease in food or fluid
0,1	Fluid output exceeds input

Range: 0–5

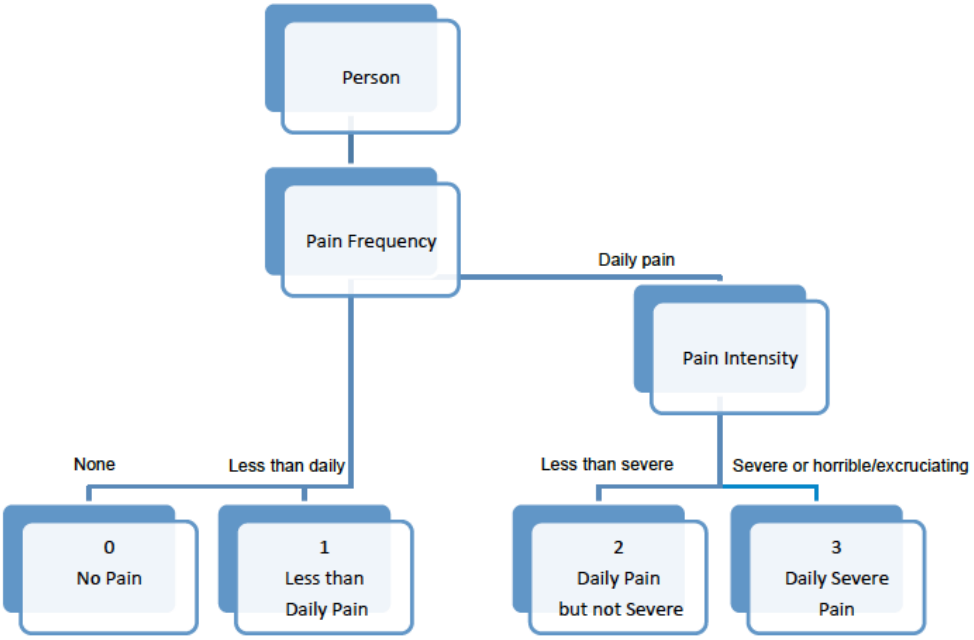
Scoring:

0 = No health instability
1 = Minimal health instability
2 = Low health instability
3 = Moderate health instability
4 = High health instability
5 = Very high health instability

The CHESS Scale is calculated by adding sign and symptom variables up to a maximum of 2, then adding three other variables (Change in decision making, Change in ADL status, and End-stage disease), giving a highest CHESS score of 5.

Source: Hirdes JP, Frijters D, Teare G. 2003.The MDS CHESS Scale: A New Measure to Predict Mortality in the Institutionalized Elderly. *Journal of the American Geriatrics Society* 51(1): 96–100.

Pain Scale

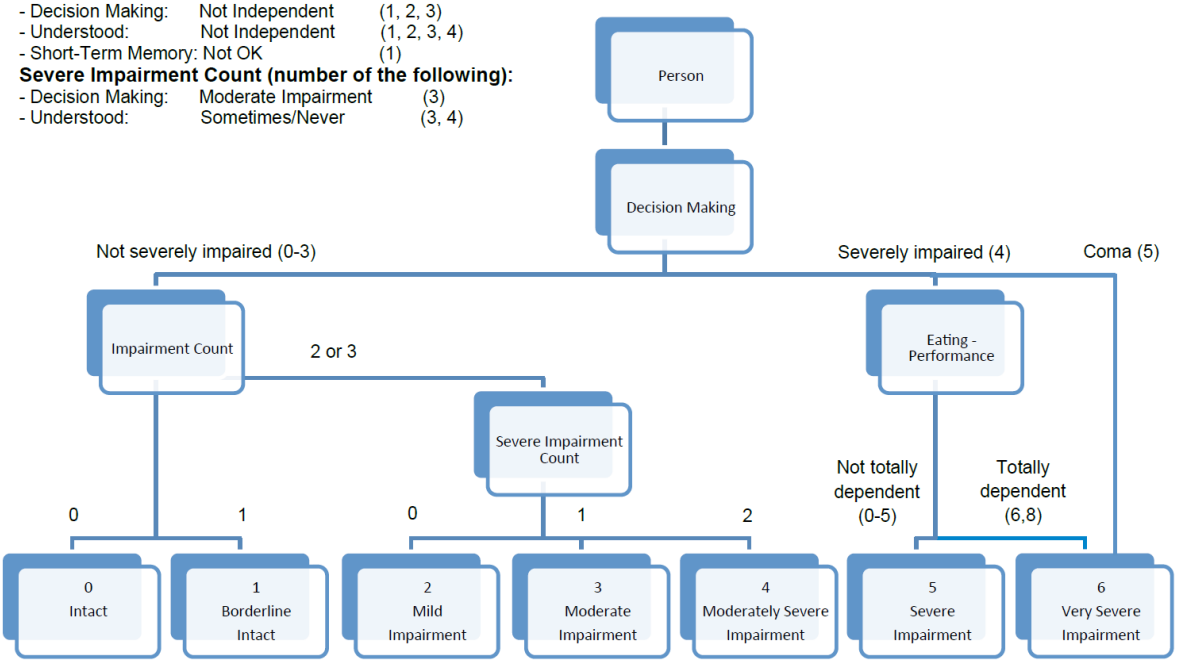


Source: Fries BE, Simon SE, Morris JN, Flodstrom C, Bookstein FL. 2001. Pain in U.S. Nursing Homes: Validating a Pain Scale for the Minimum Data Set. *Gerontologist* 41(2): 173–79.

Cognitive Performance Scale

Impairment Count (number of the following):
- Decision Making: Not Independent (1, 2, 3)
- Understood: Not Independent (1, 2, 3, 4)
- Short-Term Memory: Not OK (1)

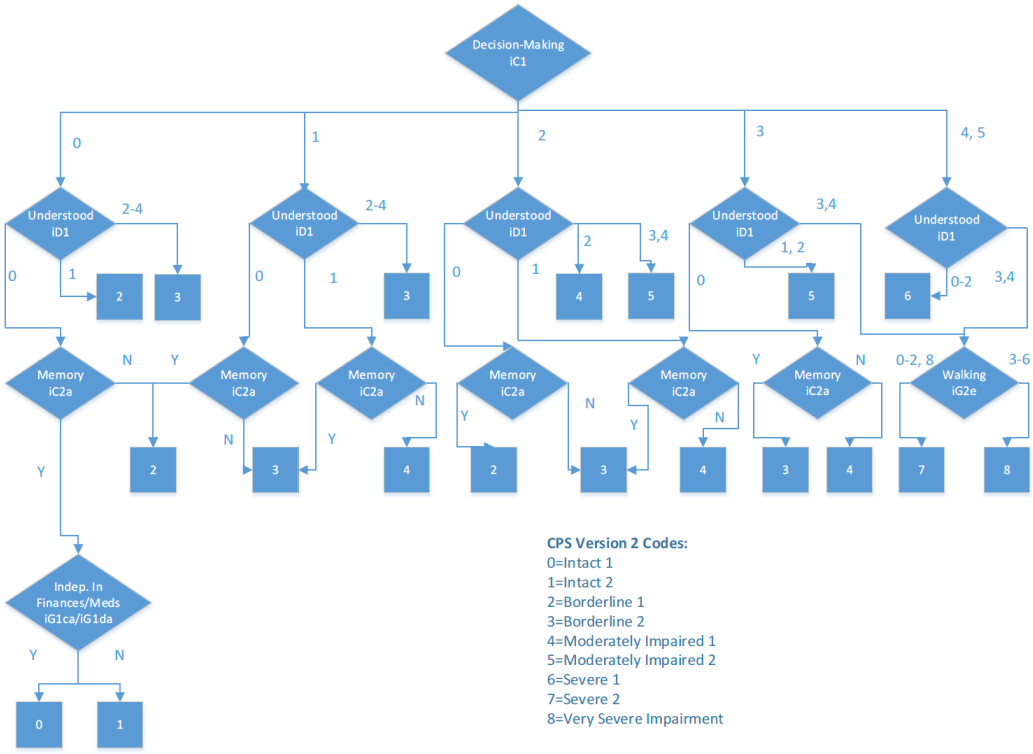
Severe Impairment Count (number of the following):
- Decision Making: Moderate Impairment (3)
- Understood: Sometimes/Never (3, 4)



Source: Morris JN, Fries BE, Mehr DR, Hawes C, Philips C, Mor V, Lipsitz L. (1994) MDS Cognitive Performance Scale. Journal of Gerontology: Medical Sciences 49 (4): M174-M182.

Cognitive Performance Scale 2

(Updated Diagram)



CPS Version 2 Codes:

0=Intact 1
1=Intact 2
2=Borderline 1
3=Borderline 2
4=Moderately Impaired 1
5=Moderately Impaired 2
6=Severe 1
7=Severe 2
8=Very Severe Impairment