

1 A multicomponent educational intervention to improve general practice registrars' prescribing of
2 benzodiazepines and related drugs: the BENEFIT study protocol for a prospective controlled
3 study.

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32 Items from the World Health Organisation Trial Registration Data Set

Data category	Information
Primary Registry and Trial Identifying Number	Australia New Zealand Clinical Trial Registry ACTRN12618000824268
Date of Registration in Primary Registry	15/05/2018
Secondary Identifying Numbers	N/A
Source(s) of Monetary or Material Support	Royal Australia College of General Practitioners Education Research Grant (002) 2017
Primary Sponsor	Professor Parker Magin
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Contact for Public Queries	Professor Parker Magin: parker.magin@newcastle.edu.au
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Public Title	Evaluation of a Multicomponent educational package for GP registrars in improving guideline compliance for prescription of benzodiazepines and related drugs in general practice.
Scientific Title	Evaluation of a multicomponent educational package for GP registrars in improving guideline compliance for prescription of benzodiazepines and related drugs in general practice: a pragmatic evaluation employing a non-equivalent control groups design nested within an ongoing cohort study, and post-intervention qualitative evaluation.
Countries of Recruitment	Australia
Health Condition(s) or Problem(s) Studied	Latrogenic harm from Potentially Inappropriate prescription of benzodiazepines and related drugs by GP registrars.
Intervention(s)	Intervention name: Education package Intervention description: 1. Pre- and Post- workshop educational resources. 2. A 40 minute registrar face-to-face educational workshop 3.A 60 minute online supervisor webinar based on the face-to-face educational workshop 4. An optional joint GP registrar/supervisor educational activity Control description: 'Usual education'.

Key Inclusion and Exclusion Criteria	<p>Inclusion: Intervention group: Registrars in Terms 1 and 2 of their vocational training program at one Regional Training Organisation (RTO) (GP Synergy).</p> <p>Control group: Registrars in Terms 1 and 2 of their vocational training program at two RTOs (GPTT and EVGP).</p> <p>Exclusion: Registrars who do not provide consent for the data they collect as part of the ReCEnT project to be used for research purposes.</p>
Study Type	<p>Observational with evaluation of the educational package being nested within an ongoing cohort study (ReCEnT).</p> <p>For the purposes of the ANZCTR format, however, we have classified the study type as Interventional.</p> <p>Method of allocation: Non-randomized: Masking: Not used: Assignment: Parallel</p> <p>Purpose: Educational/ counselling/training.</p>
Date of First Enrolment	3/5/2018
Sample size	624
Recruitment Status	Recruiting
Primary Outcome(s)	<p>Primary outcome [1]: The primary outcome factor will be 'frequency of benzodiazepine prescription' as measured by ReCEnT data. Time frame: two months pre-intervention in 2018. Post-intervention ReCEnT data will be collected four months post-intervention.</p>
Key Secondary Outcomes	<p>Secondary outcome [1] 'frequency of benzodiazepine initiation' as measured by ReCEnT data. Time frame as for Primary outcome [1].</p> <p>Secondary outcome [2]: Change in anticipated prescribing behavior as measured by responses to clinical vignettes in a questionnaire. Time frame: one month pre-intervention and two months post intervention.</p>
Ethics Review	18/04/2018 Ethics reference number: H-2009-0323
Completion date	
Summary Results	N/A
IPD sharing statement	<p>Advice from the approving ethics committee precludes making the database publicly available. Participants in the ReCEnT study have in the past not provided explicit consent for their data to be made available in this way and some of the data analyzed in this project will be of participants who have not provided that consent.</p> <p>IPD will not be shared.</p>

34 **Abstract**

35 **Background:** There are limited evidence-based indications for use of benzodiazepines and related medicines
36 (including Z-drugs) in general practice. These drugs are associated with frequent and serious adverse effects.
37 Despite this, they are frequently prescribed by general practitioners (GPs), including frequent prescribing by GPs in
38 training (in Australia termed 'registrars'). There is evidence that current educational approaches are not attenuating
39 Australian GP registrars' prescribing of benzodiazepines and related medicines.

40 We aim to evaluate the effectiveness of a multi-component educational intervention designed to decrease GP
41 registrars' prescribing of, and initiation of, benzodiazepines and related medicines.

42 **Methods/design:** We will use a pragmatic non-randomised, non-equivalent control group design nested within an
43 ongoing cohort study of registrars' practice (the Registrar Clinical Encounters in Training study; ReCEnT) to assess
44 the intervention's impact on benzodiazepine prescribing in patients 16 years-and-over.

45 The registrar educational intervention includes a face-to-face session with pre- and post-session readings, and a
46 webinar for their supervisors, plus facilitation of the registrar-supervisor dyad in weekly one-on-one in-practice
47 teaching meetings. The face-to-face session and webinar will focus on non-pharmacological management of anxiety
48 and insomnia. Facilitating in-practice teaching will include provision of frameworks for case-based discussions
49 involving non-pharmacological management of clinical scenarios that are often treated (contrary to evidence-based
50 guidelines) in general practice with benzodiazepines. The components of the educational intervention are
51 underpinned by the Behaviour Change Wheel (BCW) framework.

52 The primary outcome measure will be frequency of prescription of benzodiazepines and related drugs (including Z-
53 drugs) by registrars. The secondary outcome will be initiation of benzodiazepines and related drugs (including Z-
54 drugs). Further evaluation of the intervention will entail participant interviews (with registrars and supervisors) and
55 registrars' pre- and post-intervention questionnaire responses.

56 **Discussion:** Early-career GPs are still developing their clinical practice and prescribing habits. They are an important
57 group for educational interventions that encourage non-pharmacological management of anxiety and insomnia
58 rather than use of benzodiazepines and related drugs.

- 59 **Trial registration:** Australian New Zealand Clinical Trials Registry, ACTRN12618000824268 (registered 15/05/2018).
- 60 **Keywords:** Benzodiazepines, Hypnotics and Sedatives, General practice, Graduate medical education, Physician
- 61 prescribing patterns, Evidence-based medicine

62 Introduction

63 Background and rationale

64 A considerable evidence-practice gap exists in the area of the prescribing of benzodiazepines and benzodiazepine-
65 like drugs, including the Z-drugs, by Australian GP registrars (trainees or residents in general practice).[1] There are
66 important clinical implications for patients and health systems of a lack of adherence to evidence-based guidelines.
67 The result is an over-reliance on pharmacotherapy for the management of anxiety and insomnia.

68 Outside the infrequent (in general practice) indications such as acute alcohol withdrawal, guidelines and
69 international recommendations reserve benzodiazepines for cautious short-term use in severe or disabling anxiety
70 or insomnia. The Australian Therapeutic Guidelines: Psychotropic, state 'although commonly used to treat anxiety in
71 the past, benzodiazepines are not recommended for the treatment of these disorders other than in exceptional
72 circumstances...large numbers of patients develop problems of tolerance and abuse'.[2] American guidelines for
73 management of chronic insomnia advise cognitive behaviour therapy (CBT) and discourage benzodiazepine use (as
74 strictly second-line short-term use, if at all).[3]

75 Benzodiazepine acute phase withdrawal phenomena range from trivial to major in nature (e.g. seizures,
76 psychosis).[4] Protracted withdrawal phenomena have been described by 15-44% of benzodiazepines-users
77 following as little as 3-6 weeks use.[4] Withdrawal symptoms have been reported as lasting over a year.[4]
78 Withdrawal attempts are thus difficult, with relapse rates of 49%-57% reported.[4] Associations of benzodiazepine
79 use include: paradoxically worsening insomnia, Alzheimer's disease, falls and fractures, adverse drug reactions,
80 pneumonia, and increased mortality.[5-9] Benzodiazepines are associated with overdose, especially in combination
81 with opioids.[10, 11] Opioids and antitussives are common causes of drug interactions in benzodiazepine users.[8]
82 The combination of benzodiazepine abuse and alcohol abuse is common and particularly problematic.[12] A recent
83 authoritative systematic review has found benzodiazepines to be associated with markedly increased overall
84 mortality.[13]

85 In recent years, the Z-drugs (zopiclone, zolpidem, zaleplon) have been promoted as hypnotics and as being safer
86 than benzodiazepines[14] and this promotion has been successful in shaping GP attitudes.[15] Z-drugs, however,

87 have proven to be extremely problematic with adverse side-effect profiles comparable with benzodiazepines[16-21]
88 and with hypnotic effects of questionable clinical significance.[22]

89 Most benzodiazepines are prescribed in primary care by GPs.[23] In the Registrar Clinical Encounters in Training
90 (ReCEnT) database (now comprising over 200,000 consultations), benzodiazepines and related drugs are prescribed
91 in 2.1% of all registrar consultations and comprise 2.2% of all prescriptions.[1] Of benzodiazepine and related drug
92 prescriptions, 6.6% are for zopiclone or zolpidem.[24] They are prescribed most frequently for insomnia (28.2%) or
93 anxiety (21.8%), but half are for mainly 'off-label' indications.[1] This data also demonstrates that registrars
94 prescribe benzodiazepines mainly as maintenance therapy to patients with whom they are unfamiliar and to older
95 patients, inconsistent with current guideline recommendations.[1] This represents problematic prescribing
96 behaviour and a compelling target for behavioural-based education. The geographic variation in benzodiazepine
97 prescribing between Regional Training Organisations (RTOs: the geographically defined providers of general practice
98 training)[1] also suggests scope for behaviour change in this population of GP registrars. Educational interventions
99 to change registrars' benzodiazepine prescribing behavior could also be informed by other findings from the ReCEnT
100 study (such as Aboriginal and Torres Strait Islander patients being more likely to receive benzodiazepines, and male
101 registrars being more likely to prescribe benzodiazepines).[1]

102 Longitudinal analyses of temporal changes in overall GP registrar benzodiazepine-prescribing in the ReCEnT study
103 suggest there has been a modest reduction in overall registrar benzodiazepine prescribing rates over the period
104 2010-16, though prescribing rates remain problematically high.[24] Overall prescribing of benzodiazepines by
105 registrars (adjusted for multiple potential confounders) reduced by a statistically significant 6% per year.[24]

106 Longitudinal within-registrar analysis, however, shows that individual registrars' benzodiazepine prescribing does
107 not reduce during training.[24]

108 Thus, this is a complex situation. One interpretation of these findings is that there has been a decrease in the
109 benzodiazepine prescribing in the wider general practice environment which registrars enter on commencing GP
110 training [25]. This possibly reflects an effect of health authorities' efforts to reduce benzodiazepine prescribing in
111 the wider general practice context. This changing practice context would influence registrars who learn in an
112 apprenticeship-like training model. Our results, however, suggest that Australian GP vocational training does not

113 produce any change in registrars' benzodiazepine-prescribing and, so, does not contribute to the welcome (though,
114 thus far, insufficient) recent reduction in benzodiazepine-prescribing.

115 Hence, carefully designed and delivered educational interventions to promote rational prescribing of
116 benzodiazepines in current and future cohorts of GP registrars are much needed. Registrars are at an early stage of
117 development of clinical practices and attitudes. GP prescribing behaviours established in the early stages of their
118 career may tend to remain consistent over time.[26]

119 Our qualitative data, as well as data from ReCEnT, on antibiotic prescribing for non-pneumonia respiratory tract
120 infections suggests that structural, behavioural and educational factors in the operation of the apprenticeship-like
121 model of vocational GP training in Australia may reduce adherence to guidelines.[27, 28] Thus, interventions to
122 produce change in registrars' guideline adherence should address the supervisor-registrar dyad rather than just the
123 registrar.

124 **Objectives and hypotheses**

125 We aim to develop and test the efficacy of an educational intervention designed to reduce prescription of
126 benzodiazepine and related drugs (*hereafter, 'benzodiazepines'*), informed by a theoretical approach and current
127 evidence around interventions to influence clinician behaviour.

128 Our research question is: does a multicomponent educational intervention focusing on providing skills in non-
129 pharmacological management of anxiety and insomnia can decrease general practice registrars' prescribing of
130 benzodiazepines.

131 Our hypotheses are:

132 a) For registrars' prescribing of benzodiazepines and related drugs

133 In registrars enrolled with one Australian Regional Training Organisation who have received a multicomponent
134 educational intervention on benzodiazepine and related drugs use and non-pharmacological managements of
135 anxiety and insomnia, compared to registrars at two other Australian Regional Training Organisations who have not

136 received the intervention, there will be, for patients aged over 16 years, a greater decrease, from pre-intervention
137 to post-intervention, of

138 i) The number of benzodiazepines prescribed by registrars per 100 consultations.

139 ii) The number of benzodiazepines initiated by registrars per 100 consultations.

140 b) for 'anticipated deprescribing behaviour' assessed by questionnaire

141 In registrars of one Australian Regional Training Organisation who have received a multicomponent educational
142 intervention on benzodiazepine and related drugs use and non-pharmacological managements of anxiety and
143 insomnia, there will be an increase pre-intervention to post-intervention in the number of registrars who make
144 appropriate responses (including non-prescription of benzodiazepines) to each of several clinical vignettes involving
145 clinical scenarios of anxiety or insomnia.

146 **Study design**

147 The principal element of the **BEN**zodiazepines: **E**nhancing compliance **F**or reduced prescribing **I**n **T**raining (BENEFIT)
148 project is a pragmatic non-randomized trial employing a non-equivalent control group design, nested within an
149 ongoing cohort study, the Registrar Clinical Encounters in Training (ReCEnT) Study.[29]

150 The project design also includes a questionnaire-based pre- and post-intervention analysis and a qualitative
151 evaluation.

152 The three elements of the overall project are:

153 i) A quantitative evaluation of change in GP registrars' behaviour regarding benzodiazepine prescribing
154 and initiation in patients aged 16 years or older, as measured by ReCEnT data. Data for this analysis will
155 be collected during the six-monthly rounds of ReCEnT data collection.

156 ii) A quantitative evaluation of change in GP registrars' attitudes and knowledge regarding benzodiazepine
157 prescribing, as measured by questionnaire responses to clinical vignettes. Pre- and post-intervention
158 questionnaires will elicit participants' medication management responses to a number of general
159 practice vignettes (clinical scenarios) involving anxiety or insomnia. These clinical vignettes will be

160 designed to reflect situations where prescribing of benzodiazepines is neither recommended nor
161 warranted.

162 iii) A qualitative evaluation (involving semi-structured interviews) of: a) GP registrars' and supervisors'
163 opinions on what elements of the educational intervention worked well and how it could be improved;
164 and b) how GP registrars' practices have changed and barriers to / facilitators of such change.

165 **Methods: Participants, interventions, and outcomes**

166 **Study Setting**

167 The intervention will be delivered during a session at a routinely-scheduled educational workshop at the RTO, GP
168 Synergy. RTOs are government-funded, not-for-profit, geographically-defined GP vocational training organizations.
169 There are nine RTOs covering the whole of Australia. GP Synergy is the largest, delivering education and training
170 across the state of New South Wales and the Australian Capital Territory with an intake of approximately 500
171 registrars per year (approximately one-third of the entire Australian intake).

172 The comparator RTOs will be Eastern Victoria GP Training (covering approximately half of the state of Victoria
173 including half of the capital city, Melbourne) and General Practice Training Tasmania (covering the whole of the
174 state of Tasmania). The intervention and comparator RTOs cover the full range of Australian GP training settings
175 including practices located in all rural classifications.[30] All three RTOs participate in the ReCEnT project.

176 Within each RTO, registrars train in accredited independent practices under the supervision of an experienced GP
177 supervisor (trainer, preceptor). This supervision includes a weekly face-to-face one-on-one teaching session for
178 Term 1 and Term 2 registrars (these are the first of three 6-month full-time-equivalent compulsory general practice-
179 based terms in registrars' 3-year vocational training program). Registrars also receive structured away-from-practice
180 teaching organized by their RTO (at least 125 hours in total in Term 1 and Term 2).

181 **Eligibility criteria**

182 Participants will be Term 1 and Term 2 (that is, in the first 12 months of GP training for a full-time registrar) GP
183 registrars at the three RTOs. The intervention to GP Synergy registrars will be conducted as part of their routine
184 training program.

185 *Inclusion criteria*

186 For the analysis using ReCEnT study data: The intervention group will consist of registrars in Terms 1 and 2 of their
187 vocational training program at one RTO (GP Synergy). The comparator group will consist of registrars in Terms 1 and
188 2 of their vocational training program at two RTOs (General Practice Training Tasmania – GPTT: and Eastern Victoria
189 GP Training – EVGP).

190 For the questionnaire-based study: Participants will be registrars in Terms 1 and 2 of their vocational training
191 program at one RTO (GP Synergy).

192 For the qualitative study: Participants will be registrars in Terms 1 and 2 of their vocational training program at one
193 RTO (GP Synergy) and supervisors of GP Synergy registrars.

194 *Exclusion criteria*

195 For the analysis using ReCEnT study data: Registrars who do not provide consent for the data they collect as part of
196 the ReCEnT project to be used for research purposes.

197 For the questionnaire-based study: No exclusions.

198 For the qualitative study: registrars or supervisors who have not attended the workshop or webinar

199 **The intervention**

200 The educational intervention consists of several components. The first two components, a face-to-face session and
201 associated pre-workshop readings, will be delivered to GP registrars.

202 The third component is a webinar for the supervisors of these registrars that will be based on the content of the
203 face-to-face presentation. Supervisors will also be provided with pre-webinar readings.

204 The fourth component is an optional joint GP registrar-supervisor education activity for each registrar-supervisor
205 dyad to use in their regular weekly one-on-one teaching meetings.

206 The face-to-face registrar educational session will be delivered as a 40-minute session. The supervisor educational
207 intervention via webinar will be delivered as a one-hour session.

208 The first three components of the intervention will be delivered in June 2018 during General Practice Training Term
209 2018.1. The fourth component will be delivered at the discretion of supervisors and registrars during the first two
210 months (July-August) of General Practice Training Term 2018.2.

211 *Theoretical framing of intervention content*

212 Interventions aimed at improving clinical practice often require behaviour change among health care providers. The
213 Behaviour Change Wheel (BCW)[31] was chosen as a framework to guide intervention development as it provides a
214 systematic approach through the steps of understanding the target behaviour, identifying relevant intervention
215 functions and specifying intervention content. The BCW has also previously formed a basis of a benzodiazepine
216 deprescribing intervention for older patients.[32]

217 Given current high levels of benzodiazepine prescribing,[1] having registrars comply with current guidelines for use
218 of benzodiazepines will require considerable changes in behavior. The BCW consists of three layers or phases,
219 offering a step-by-step method for designing behaviour change interventions. The first stage in the BCW theoretical
220 guide helps researchers identify the potential predictors of the behaviour(s), known as COM-B, standing for
221 ‘capability’, ‘opportunity’, ‘motivation’ and ‘behaviour’, which would need to change to address the core health
222 problem(s). The second phase in the theoretical process involves the analysis of nine key intervention functions
223 (education, persuasion, incentivization, coercion, training, restriction, environmental restructuring, modelling and
224 enablement), depending on the particular COM-B analysis, which can facilitate a change in a behaviour.[31] It also
225 outlines the individual behaviour change techniques (BCTs), which can best change the behaviours. In total, there
226 are 93 BCTs within 16 groupings. The third, outer, layer (the rim of the wheel) identifies seven policy areas, which
227 one could employ to change the behaviour. To address appropriate de-prescribing, registrars/GPs must have the
228 appropriate capability (which can be physical or psychological) to address knowledge, skills and stamina to perform

229 the behaviour. There must also be the opportunity for the appropriate prescribing to occur, in terms of a conducive
230 physical and social environment. The capability and opportunity to do the behaviour leads to motivation, which can
231 be reflective or automatic. Registrars' 'Sources of Behaviour' ('Capability, Opportunity, and Motivation') in relation
232 to de-prescribing will be addressed by intervention elements addressing Education, Persuasion, Training,
233 Enablement, Modelling, and Environmental restructuring (six of the nine BCW 'Intervention Functions'). See Table 1.

234 PLACE TABLE 1 ABOUT HERE

235 *Components of the intervention: Workshop pre-reading*

236 Three journal papers will be made available to registrars and supervisors. These cover the areas of benzodiazepine
237 misuse and dependence [33], anxiety management [34], and non-pharmacological management of insomnia [35].

238 The pre-workshop readings will be made available to registrars and supervisors two weeks prior to the face-to-face
239 session and webinar, respectively.

240 *Components of the intervention: Educational workshop session*

241 The face-to-face workshop session will consist of a 40-minute educational presentation to approximately 450
242 registrars, scheduled as part of the standard training program for GP registrars delivered at GP Synergy RTO. The
243 face-to-face session will be led by an addictions specialist who is also a GP and supervisor of GP registrars. The
244 session will be co-delivered by an experienced clinical psychologist with particular expertise in the education of non-
245 psychologists in non-pharmacological anxiety and stress management strategies.

246 In this face-to-face session, data on GP registrars' benzodiazepine prescribing collected in the ReCEnT project will be
247 used to contextualize and reinforce the practical relevance and importance of the educational message (the ReCEnT
248 data will be that of registrars who have participated in ReCEnT during 2010 to 2017). Time will be devoted to the
249 practicalities of how to teach patients distracting, mindfulness, and relaxation / self-calming techniques within a
250 general practice setting. Collaborative models of registrars, supervisors and practices working together to
251 implement appropriate practices and policies regarding benzodiazepine use will be promoted.

252 Post-session supporting resources will be available as links in a post-workshop email to reinforce the workshop and
253 provide practical resources including links to a sleep diary for patient use; patient information materials concerning
254 sleep hygiene and management of stress and anxiety and simple Cognitive Behaviour tools for dealing with anxiety;
255 and e-Mental Health Programs.

256 The workshop session content will be constructed by the research team consisting of GPs, GP vocational training
257 educators, academic GPs, addictions specialists and a clinical psychologist. The process will be informed by the
258 current literature in the area and our recent work in documenting GP registrars' benzodiazepine prescribing,
259 including the prevalence and associations of this prescribing[36].

260 *Components of the intervention: Webinar for supervisors*

261 The webinar content will be based on the content of the registrar face-to-face session. The webinar will also
262 emphasize the need for supervisors to work towards practice cultures where registrars' evidence-based
263 management of anxiety and insomnia, and appropriate use of benzodiazepines is supported. The role of the
264 supervisor and registrar working collaboratively in managing patients who may have an expectation of
265 benzodiazepine prescription, or in managing safe withdrawal of patients from benzodiazepines, will be explored.

266 *Components of the intervention: Joint registrar/supervisor activity*

267 Each registrar-supervisor dyad will be encouraged to include a case-based discussion of appropriate management of
268 anxiety and insomnia, and of avoidance of benzodiazepine use, in their regular weekly one-on-one teaching
269 meetings. The supervisor will be offered a set of three structured cases to include in the meeting. The supervisor
270 and registrar will also be encouraged to perform an informal audit and notes review of patients who have received
271 benzodiazepine prescriptions from registrar or supervisor. The joint registrar/supervisor activity will be optional as
272 the content of registrar-supervisor weekly meetings is at the discretion of the supervisor and registrar rather than
273 the RTO.

274 *Rationale of intervention components*

275 Reducing benzodiazepine prescribing involves changing clinicians' (in this case, registrars') behaviour. In keeping
276 with the overarching theoretical framing of the intervention within the BCW, aspects of the intervention were

277 informed by a number of evidence sources. We have also designed our intervention components, where possible, to
278 be consistent with modalities for which there is evidence of efficacy in changing clinician behavior. We incorporated
279 the findings of the Cochrane Collaborations Effective Practice and Organisation of Care (EPOC) Review Group,
280 wherever possible, in our intervention components.[37]

281 The rationale for supplementing the educational intervention with supervisor and joint registrar-supervisor
282 educational activities is the registrar-supervisor relationship which is the key factor in registrar training. [38-41] Our
283 previous research has suggested that the prescribing patterns (role-modelling) of supervisors and the
284 ‘apprenticeship’ model of the registrar-supervisor relationship are drivers of inappropriate antibiotic prescribing
285 behaviour [42-44]. It is likely that these will have similar influence on inappropriate (or appropriate) benzodiazepine
286 prescribing.

287 Thus, registrars working collaboratively with supervisors within shared-care models and within supportive practice
288 environments is likely to be an optimal approach to avoidance of inappropriate benzodiazepine prescribing. Close
289 shared-decision making will also be vital in supporting registrars in maintaining patient safety when benzodiazepine
290 withdrawal is indicated. In designing the various components of our intervention, we have recognized the
291 importance of the registrar-supervisor dyad and attempted to ground our suggested strategies in an understanding
292 of how the dyadic relationship works in practice, including the varying degrees of registrar involvement/autonomy in
293 shared management plans and decisions [45].

294 Educational meetings alone or combined with other interventions, can improve professional practice [46] and we
295 will have the registrar workshop session and supervisor webinar as central elements of our educational package.
296 Educational meetings in isolation, however, have limited capacity to effect change in complex behaviours [46]. We
297 will employ other strategies in addition to our workshops. We will set the scene for our educational meetings with
298 background materials designed to suit the needs of clinicians.

299 Audit and feedback have been found to lead to small but potentially important improvements in professional
300 practice [47] and feedback may be more effective when the source is a supervisor or colleague [47]. A traditional
301 audit process is not practicable for our educational package, but we will be encouraging supervisors and registrars

302 to perform an informal audit of the clinical notes of patients identified as having recently received a benzodiazepine
303 prescription. We suggest that this process should prompt joint discussion and feedback from the supervisor to the
304 registrar.

305 Opinion leaders may positively influence clinicians' professional practice [48] . The main presenter at both the
306 registrar session and supervisor webinar will be a clinician who practices both as an addictions specialist and as a GP.
307 He is also an experienced supervisor of GP registrars, has published frequently on clinical drug and alcohol issues in
308 journals and periodicals widely read by Australian GPs [49-52] and presented widely on these issues at GP meetings
309 and conferences. Consistent with the EPOC group's findings,[48] we will have as a co-presenter at the supervisor
310 webinar another 'local' opinion leader within the supervisor community – a senior GP supervisor.

311 'Tailored' interventions take into account determinants of the participants' target behavior. They have been found
312 to have small to moderate effect size [53]. We will specifically address known factors in GPs' prescribing of
313 benzodiazepines [54-56]. We will also expressly address the perception of some GPs of a lack of alternatives to
314 benzodiazepine prescription [55] and the perceived barriers, for other GPs, to delivering or referring for non-
315 pharmacological alternative-to-benzodiazepine therapies, despite acknowledging their appropriateness.[56]

316 Educational meetings are more efficacious when they are interactive [46]. We are limited by structural aspects of
317 our face-to-face session with registrars (the size of the audience and venue) but we will encourage supervisor
318 interaction in the webinar.

319 *Comparator group procedures*

320 The 'comparator group' of registrars training with two other RTOs will receive "usual education" during the study
321 period. Usual education comprises teaching/education as scheduled by the comparator RTOs and will include some
322 education on benzodiazepines, anxiety and insomnia. 'Usual education' will not include the supervisor webinar nor
323 provision of materials for use in registrar-supervisor practice-located teaching sessions.

324 **Outcomes**

325 *Primary outcomes*

326 The primary outcome will be:

327 • Change in the number of benzodiazepines prescribed by registrars per 100 consultations with patients
328 aged 16 years or older. The number of benzodiazepines prescribed per 100 consultations with patients
329 aged 16 years and older will be calculated using prescribing data recorded in-consultation by each
330 registrar each six-months as part of the ReCEnT cohort study.

331 *Secondary outcomes*

332 Secondary outcomes will be:

333 i) Change in the number of benzodiazepines initiated by registrars per 100 consultations with patients
334 aged 16 years or older. The number of benzodiazepines initiated per 100 consultations with patients
335 aged 16 years and older will be calculated using prescribing data recorded in-consultation by each
336 registrar each six-months as part of the ReCEnT cohort study.

337 ii) Change in 'intended' or 'anticipated' benzodiazepine prescribing as measured by responses to clinical
338 vignettes in a questionnaire. Responses will be via multiple choice options of actions in response to
339 each clinical vignette and will be classified as 'appropriate management (including no benzodiazepine)
340 chosen' or 'appropriate management not chosen'. This outcome will apply only to intervention group
341 registrars. Comparator group registrars will not participate in the questionnaire study. This outcome
342 will be measured one-month pre-intervention and two months post-intervention.

343 iii) Registrars' and supervisors' experiences of undertaking the intervention as measured by semi-
344 structured qualitative interview. This outcome will be measured two-four months post-intervention.
345 This outcome will apply only to intervention group registrars and supervisors. Comparator group
346 registrars or supervisors will not participate in the qualitative study.

347 'Benzodiazepines' (that is, 'benzodiazepines and related drugs') will be defined as International Anatomical
348 Therapeutic Chemical codes 'N05B' and 'N05C'.

349 *Rationale of outcomes*

350 The ReCEnT data is a 'snap-shot' of individual consultations. We do not have data on previous or follow-up
351 consultations and we do not have information of patients' past medical history or drug regimens. We only have data

352 on the conditions managed in the index consultation and the medicines prescribed in the index consultation.
353 Without the contextual data, we are unable to ascertain the appropriateness or inappropriateness of the decision to
354 prescribe in individual instances of benzodiazepines prescription or initiation. But given the infrequency of indication
355 for benzodiazepines in general practice, overall prescribing and initiation data will be a robust measure of overall
356 levels of inappropriate benzodiazepine prescribing and initiation.

357 The secondary analysis is of benzodiazepines initiations (newly-prescribed benzodiazepines). There will be different
358 consultation and therapeutic dynamics operating for benzodiazepine initiation than for prescription
359 renewal/continuance. Patient expectations of a benzodiazepine script will be different for script renewal as opposed
360 to new management [57]. The considerable issue of potential benzodiazepine withdrawal symptoms [33] will also
361 make benzodiazepine deprescribing more complex and difficult to negotiate than initial non-prescription. A further
362 factor is the registrar's junior status. Just as GPs find difficulty in discontinuing inappropriate medicines initially
363 prescribed by specialists [58], registrars may find it difficult to discontinue medicines initiated by their supervisor or
364 another senior GP in their practice. There is certainly evidence of this pressure in registrars' prescription of
365 antibiotics for patients for whom their supervisor or other senior GP has previously prescribed them [27].

366 Triangulation of findings of the secondary analysis of 'intended' or 'anticipated' prescribing (elicited in the vignette-
367 based questionnaire) and those of the primary analysis of 'actual' prescribing (elicited via ReCEnT data) will provide
368 evidence of the relative impact of the intervention on registrar knowledge and attitudes as opposed to impact on
369 registrar practice. This will have implications for understanding the role of practice 'clinical milieu' versus specific
370 educational process in registrar training and registrar behavior.

371 **Sample size calculation**

372 *Project element 1: Primary analysis- evaluation of change in registrars' benzodiazepine prescribing*

373 There will be approximately 450 registrars from the intervention RTO eligible to attend the face-to-face educational
374 session and approximately 624 registrars, in all, with post-intervention data. Power-sample size calculations are
375 based on this.

376 Assuming a similar pre-intervention prescribing rate in comparator and intervention consultations, and that the
377 comparator group shows no change in prescribing rates from pre- to post-intervention, power has been estimated
378 based on detectable differences in prescribing rates between intervention and comparator groups, post-
379 intervention.

380 We have estimated the detectable effect size assuming a total sample size of 29,952 encounters with patients aged
381 >16 years for 624 registrars, post-intervention. The intervention to comparator allocation ratio is approximately 2.7:
382 1. Assuming a benzodiazepine prescribing rate of 2.2 % in comparator consultations, we will have 80% power to
383 detect a prescribing rate of 1.7 % in intervention consultations, post-intervention, at a two-sided significance level of
384 0.05. This corresponds with a 23% decrease in the prescribing rate (Relative risk (RR) = 0.77). Allowing for potential
385 clustering of prescribing rates within registrars, assuming possible ICCs of either 0.01 or 0.02, we will be able to
386 detect post-intervention prescribing rate decreases of 27% (RR=0.73) and 31% (RR=0.69). This assumes each
387 registrar has 48 encounters, corresponding to Design Effects of 1.47 and 1.94, respectively.

388 **Recruitment**

389 *Project element 1: Evaluation of change in registrars' actual deprescribing.*

390 No additional recruitment will be required for this component. Participants will be Term 1 and 2 registrars enrolled
391 in the three participating RTOs and will undertake ReCEnT project data collection as a routine part of their training
392 programs.

393 *Project element 2: A quantitative evaluation of change in GP registrars' attitudes and knowledge regarding
394 medicines deprescribing, as measured by questionnaire responses to clinical vignettes*

395 All Term 1 and Term 2 registrars at the intervention RTO will be approached by both email and post inviting them to
396 complete the study questionnaire four weeks prior to the intervention. There will be a single follow-up email
397 invitation to non-responders two weeks later. The sample frame will be the enrolment lists of the participating RTO.
398 Post-intervention questionnaires will be sent to registrar participants by email and hard copy mailout two months
399 post-intervention. A follow-up reminder email will be sent two-three weeks after distribution of the post-
400 intervention questionnaire.

401 *Project element 3: a qualitative evaluation of GP registrars' and supervisors' experience of the educational*
402 *intervention.*

403 All Intervention RTO registrars who have attended the face-to-face workshop session and all supervisors who have
404 attended the webinar will be approached by both email and post inviting them to participate in either phone or
405 Skype or Zoom interviews.

406 A reminder email will be sent two-three weeks following the initial invitation. The sample frame will be the
407 attendance lists of the face-to-face workshop session and webinar.

408 Selection of responding registrars and supervisors for invitation will be purposive, based on age, gender, rurality of
409 practice, place of graduation (Australian versus international). If possible, some registrar-supervisor dyads will be
410 recruited.

411 **Methods: Assignment of interventions (for controlled trials)**

412 Assignment to intervention or control will not be random. Assignment will be at the level of RTO and on the basis of
413 willingness and capacity of the intervention RTO to include the benzodiazepine prescribing intervention within their
414 routine educational program.

415 A randomized control trial design is not appropriate for the BENEFIT evaluation of change in registrars'
416 benzodiazepine prescribing. Regarding assignment to intervention or control at the level of RTO: assignment at the
417 level of registrar or of other smaller units within the RTOs is impracticable. Registrars within each RTO share regular
418 educational and professional contacts (for example, at RTO-delivered face-to-face educational sessions). Thus,
419 assignment at levels less than RTO will result in risk of contamination.

420 Cluster randomization at the RTO level is also not viable. There are only three RTOs participating in the ReCenT
421 cohort study in which BENEFIT is nested. With a major reorganization of Australian vocational training in 2016 there
422 are now only nine RTOs covering the whole of Australia.

423 Finally, the educational programs in which the intervention is to be included are crowded, with multiple topics
424 competing for inclusion (necessitating considerable negotiation to justify a regular teaching place for a new session).

425 These are, furthermore, set up to 12 months in advance. Randomization of teaching sessions within their
426 educational programs is not acceptable to RTOs.

427 The non-random allocation will be considered during analyses via multivariable analyses utilizing the large number
428 of potential confounding variables measured in ReCEnT.

429 **Independent variables measured in the ReCEnT project**

430 Independent variables relate to registrar, patient, practice and consultation factors.

431 *Registrar factors* will be age, gender, training term at the time of the intervention (Term 1 or Term 2), place of basic
432 medical qualification (dichotomized as Australia or international), if the registrar worked at the practice during a
433 previous term, the RTO with which the registrar is enrolled, registrars' year of medical graduation, duration of pre-
434 GP training time spent in hospital practice, and registrars' full-time/part-time status.

435 *Patient factors* will be age, gender, Indigenous (Aboriginal or Torres Strait Islander) status, non-English-speaking
436 background, if the patient is a new patient to the practice and if the patient is new to the registrar.

437 *Practice factors* will be level of rurality of the practice location, practice size (number of full-time equivalent GPs
438 dichotomized to 'large' (greater than five full-time equivalent GPs) or 'small' (less than six full-time equivalent GPs),
439 socio-economic status of the practice location, and if the practice routinely bulk bills (that is, patients pay no fee for
440 the consultation). Practice postcode is used to define the Australian Standard Geographical Classification-
441 Remoteness Area (ASGC-RA[59]) classification (the degree of rurality) of the practice location and to define the
442 practice location's Socioeconomic Index for Area (SEIFA[30]) Relative Index of Disadvantage.

443 *Consultation factors* will be duration of consultation (in minutes), the number of diagnoses/problems dealt with in
444 the consultation, if the diagnosis/problem was new or was existing, if the problem/diagnosis was a chronic disease
445 (classified according to an existing classification system), if pathology test/s was/were ordered, if imaging test/s
446 was/were ordered, if follow-up was organized, if specialist referral was made, if the registrar sought clinical
447 information during the consultation from a specialist or from electronic or hard-copy resources, and if the registrar
448 generated a learning goal related to the problem/diagnosis.

449 **Methods: Data collection, management, and analysis**

450 **Data collection**

451 *Project element 1: Evaluation of change in registrars' actual deprescribing.*

452 No data will be collected beyond data already routinely collected in ReCEnT.

453 ReCEnT is an ongoing prospective multi-site cohort study of GP registrars/registrar's consultations. From 2010 to
454 2015 it was conducted in five of Australia's then 17 GP Regional Training Providers (RTPs) [60, 61] and from 2016 it
455 has been conducted in three of Australia's nine RTOs (following the 2016 major restructure of Australia's general
456 practice vocational training program).

457 ReCEnT longitudinally documents the nature and association of consultation-based clinical and educational
458 experiences of GP registrars. Registrars record details of 60 consecutive consultations at approximately the midpoint
459 of three six-month (full-time equivalent) terms based in general practices. Details are recorded on paper-based Case
460 Report Forms and include patient demographics, diagnoses/problems managed, medications prescribed,
461 medications ceased, investigations ordered, referrals made, follow-up arranged, information/assistance sought
462 during the consultation (including supervisor advice and recourse to other sources of information – hard copy,
463 electronic, specialist doctor), and learning goals generated. Only data of office-based consultations (not home visits
464 or nursing home visits) are recorded.

465 Registrar characteristics and the characteristics of the practice they are currently training in are also documented via
466 paper-based questionnaires.

467 ReCEnT is an integrated part of the registrars' training program and includes reflection on practice and future
468 training directions via detailed feedback [60, 61]. The majority of GP registrars consent to the data also being used
469 for research purposes. As a result, participation and retention rates are singularly high for studies of GPs – greater
470 than 95%.

471 *Project element 2: A quantitative evaluation of change in GP registrars' attitudes and knowledge regarding*

472 *benzodiazepine prescribing, as measured by questionnaire responses to clinical vignettes*

473 Term 1 and Term 2 registrars at the intervention RTO will complete pre- and post-intervention questionnaires.
474 Participants will have the option of completing the questionnaire as a hard-copy or electronically via REDcap, a web
475 application for managing online surveys.

476 The questionnaire will contain several clinical vignettes consistent with clinical presentations of patients in
477 registrars' practice, comprising scenarios where benzodiazepine prescribing would be inappropriate. Registrars will
478 be asked to respond to multiple choice options as to how they would manage these vignettes.

479 The questionnaire responses will be linked to the registrar's ReCEnT data via a unique identifier which will enable us
480 to use demographic data collected during ReCEnT.

481 Participant retention and follow-up will be promoted through articles in the GP Synergy monthly Training Update
482 newsletter (delivered electronically to all registrars monthly).

483 *Project element 3: A qualitative evaluation of GP registrars' and supervisors' experience of the educational*
484 *intervention.*

485 Data collection will employ one-on-one interviews conducted by phone or Skype or Zoom (as elected by the
486 participant registrar or supervisor). Interviews will be informed by an interview schedule based on the study aims
487 and the literature but will be informant-led as much as possible and themes emerging from the interviews will
488 iteratively inform revisions of the interview schedule.

489 Recruitment will continue until thematic saturation is deemed to have occurred (no new themes are emerging from
490 the interviews).

491 *Project documents*

492 The ReCEnT Case Report Form, registrar demographics form, and practice characteristics form; BENEFIT pre- and
493 post-intervention questionnaires; and BENEFIT qualitative study interview guide can be found at the BENEFIT
494 project page in the GP Synergy NSW and ACT Research and Evaluation Unit sub-website at:

495 <https://research.gpsynergy.com.au/>

496 **Data management**

497 *Project element 1*

498 All ReCEnT data collected is de-identified. Each GP registrar is allocated a unique numerical code to protect privacy
499 which will be used on all survey forms instead of names. The de-identified ReCEnT data is entered at GP Synergy's
500 premises into a Heroku secure on-line international computer database which is run by a USA-based organization.
501 The list linking GP registrars name and ID number is stored separately in a password protected computer file at GP
502 Synergy which is only accessible by specified members of the research team.

503 *Project element 2*

504 Electronic questionnaire data will be collected and managed using REDcap electronic data capture tools [62] hosted
505 at Hunter Medical Research Institute (HMRI) in Newcastle, Australia. Any paper questionnaires will be transferred to
506 the REDcap database, at which time the paper copy will be destroyed. Participant email addresses will be stored in a
507 REDcap project "Participant list" module intended for sending emails and tracking responders/non-responders.
508 Questionnaire responses are stored on a separate module. This means that at no stage will the participants' email
509 addresses be directly linked to the survey responses. The ability to join these two modules is restricted and
510 accessible only by authorized users. The REDcap participant list and survey responses will be stored on a password-
511 protected server at HMRI with access permitted only by project personnel or HMRI authorised staff directly involved
512 in the project. Research-related datasets are stored indefinitely by HMRI unless requested to archive by the study
513 Chief Investigator or expire in a set timeframe.

514 *Project element 3*

515 Any information collected by the researchers which might identify participants will be removed from the interview
516 transcripts. The transcripts will be stored securely. The transcript can only be accessed by the researchers. Interview
517 data will be analysed and themes that emerge will be reported in an aggregated format and individuals will not be
518 identified/identifiable in any findings reported. The data will be stored securely for at least five years on GP
519 Synergy's password protected computer system prior to being destroyed in accordance with State and
520 Commonwealth legislation.

521 **Statistical methods**

522 *Analysis of benzodiazepine prescribing behaviour (Project element 1)*

523 Change in GP registrars' benzodiazepine prescribing behaviour will be assessed via ReCEnT data pre- and post-
524 intervention. The changes in GP registrars' prescribing will be compared with the changes of GP registrars of the two
525 RTOs who are not receiving the intervention (comparator group). Analysis will employ ReCEnT data 2010-2018.
526 Analyses will employ univariate and multivariable logistic regression within the Generalised Estimating Equation
527 (GEE) framework to account for repeated measures within registrars. The unit of analysis will be consultations
528 involving patients over 16 years and the outcome factor will be benzodiazepines prescribed (dichotomous yes/no).
529 Independent variables in the model will be treatment group (intervention/comparator), time (before/after) and an
530 interaction term of treatment group by time. The p-value of the interaction term will be used to determine
531 statistical significance. 'Intention to treat' and 'as treated' analyses (all intervention registrars, and workshop
532 attendees only, respectively) will be conducted.
533 Due to the high participation and retention rates in ReCEnT it is not anticipated that imputation will be required in
534 the analyses.

535 *Analysis of 'anticipated benzodiazepine prescribing behaviour' questionnaire-based evaluation (Project element 2)*
536 McNemar's test will be used to assess changes in registrars' questionnaire responses to each clinical vignette pre-
537 and post-intervention.

538 *Analysis of qualitative evaluation (Project element 3)*

539 Thematic analysis will be employed [63].

540 Data collection and analysis will be iterative and concurrent. Inductive thematic analysis will employ a process of
541 constant comparison with emerging themes being identified for further exploration in subsequent interviews.

542 Analyses will consider commonalities and differences in registrar and supervisor responses. If interviews have been
543 conducted with both parties of a registrar-supervisor dyad, this relationship will be considered in analysis.

544 Independent coding will be conducted by two researchers - the principle qualitative researcher (who will have
545 conducted the interviews) and a further study investigator. Differences in researcher perspective in interpretation of
546 the transcripts will be resolved by negotiation.

547 From this process of coding and negotiation a codebook will be developed. The codebook will be iteratively revised
548 as new transcripts are analyzed. The resultant codes will be mapped and organized into second order 'themes' and
549 named and applied to the transcripts.

550 **Methods: Monitoring**

551 The nature of the study is of an evaluation of a discrete educational package nested in an ongoing cohort study.
552 Thus, interim analyses and stopping guidelines are not appropriate and a separate Data Monitoring Committee is
553 not required.

554 **Discussion**

555 The evidence for most benzodiazepine prescription in general practice being inappropriate is strong. Thus, reduction
556 of GPs' benzodiazepine prescribing rates has been a priority in Australia [64].

557 Despite the compelling evidence supporting reduction of benzodiazepines prescribing (both initiation and ongoing
558 prescription), considerable barriers exist to reducing benzodiazepine prescription in general practice. These barriers
559 are particularly problematic in the practice of early-career, less experienced, GPs and registrars. Our ReCEnT data
560 suggests benzodiazepine prescribing by GP registrars is relatively common and does not reduce with time in training
561 (that is, with moving from Term 1 to Term 2 to Term 3). This suggests current educational strategies in Australian GP
562 vocational training relating to benzodiazepine prescription are not having the desired effect. In turn, this suggests
563 current educational strategies have not overcome the identified barriers to evidence-based use of benzodiazepines
564 in general practice.

565 In this study we aim to address the evidence-practice gap of abundant evidence for the harms of benzodiazepines
566 yet common prescription of these medicines by GP registrars. We will do this via a multicomponent educational
567 intervention that aims to decrease registrars' benzodiazepine prescribing. The intervention will include 'positive'
568 components (providing registrars with practical non-pharmacological skills for managing anxiety, stress and
569 insomnia) as well as commonly employed strategies that may be considered, in isolation, 'negative' (education
570 regarding the harms of benzodiazepines).

571 In the proposed study we target educational interventions to early-career GPs who may be thought to be
572 establishing prescribing behaviours likely to persist into later practice. This is also an efficient process – the
573 intervention is delivered within the context of an existing educational program and the infrastructure to deliver the
574 intervention already exists. The efficacy of the educational intervention will be evaluated utilizing ReCEnT study
575 data, thereby allowing an efficient integration with a concurrent education and research project[19].
576 The concurrent evaluation of change in registrars’ anticipated (vignette-based) benzodiazepine prescribing and
577 actual (ReCEnT-measured) prescribing will provide insights into limitations of the translation of educational changes
578 in knowledge and attitudes to clinical behaviours. Together with our qualitative evaluation this will facilitate
579 iterations to the educational package in annual delivery to future GP registrar cohorts. It will also have implications
580 for clinical educational practice more generally.

581 *Limitations of the project*

582 In our non-randomized trial, inferences of causality will be less strong than for an RCT. An RCT, however, is
583 impractical for this research question. Individual RTOs will only participate if it is practicable to introduce the
584 intervention into existing educational programs. Initially, for this educational intervention, this is only practicable for
585 GP Synergy. We will, however, adjust for the non-randomized design with multivariable analyses. The large set of
586 independent variables recorded in ReCEnT allows for fine-grained adjustment for confounding in these analyses. We
587 are confident that our design is the most robust approach to the research question in the context of Australian GP
588 vocational training and we have used this methodology previously with interventions addressing other GP registrar
589 clinical behaviours.[44, 65]

590 *Further implications*

591 We will introduce an educational innovation within the singular setting of GP training and the registrar-supervisor
592 dyad. If the intervention is successful, the multicomponent model developed for the BENEFIT study could also be
593 used as a basis of interventions for testing in trials targeting established GPs.

594 **Declarations**

595 **Ethics approval and consent to participate**

596 Ethical approval for the RecEnT and BENEFIT projects has been granted by the Human Research Ethics Committee
597 from the University of Newcastle (reference, H-2009-0323).

598 **Consent**

599 Benzodiazepine prescribing behaviour (Project element 1): Registrars complete ReCEnT as an integral part of their
600 education and training program. They may choose to provide informed written consent for the data collected to
601 also be used for research purposes.

602 'Benzodiazepine prescribing behaviour' questionnaire-based evaluation (Project element 2): potential participants
603 will be provided with an appropriate Information Statement accompanying their invitation to participate. Return of
604 a completed questionnaire will be deemed to constitute consent to participate. Participants will have the option of
605 linking their questionnaire data to their ReCEnT data in lieu of providing demographic data within the questionnaire.

606 Qualitative evaluation (Project element 3): Potential participants will be provided with an appropriate Information
607 Statement and will provide written consent.

608 **Confidentiality**

609 Benzodiazepine prescribing behaviour (Project element 1) and 'Anticipated benzodiazepine prescribing behaviour'
610 questionnaire-based evaluation (Project element 2): All data is and will be de-identified with each registrar having a
611 unique identifier number. The participant list and de-identified data will be stored in separate password-protected
612 computer locations.

613 Qualitative evaluation (Project element 3): Audio recordings of interviews will be transcribed by a transcribing
614 service, and names of participants will be replaced by numerical codes. Transcript content which might identify
615 participants will be removed from the transcripts. The data will be stored securely on a password protected
616 computer system.

617 **Declaration of interests**

618 All investigators declare no financial or other competing interests.

619 **Access to data**

620 The database for the study will be available to the study investigators.

621 **Dissemination policy**

622 Findings from the study will be communicated to participants via routine communications from their RTO, for
623 example the GP Synergy Training Updates for registrars and supervisors.

624 There will be no restrictions on publication or presentation to disseminate study findings to health care
625 professionals and the public.

626 There will be no use of professional writers for publications reporting study findings.

627 Advice from the approving ethics committee precludes making the database publicly available. Participants in the
628 ReCEnT study have in the past not provided explicit consent for their data to be made available in this way and some
629 of the data analyzed in this project will be of participants who have not provided that consent.

630 **Administrative information**

631 **Protocol version**

632 Protocol version 1, dated 1/5/18. Important protocol modifications (e.g. changes to eligibility criteria, outcomes,
633 analyses) will be reported to relevant parties (e.g., investigators, HREC, ANZCTR, RACGP grant regulators, journals).

634 **Trial registration**

635 The intervention is registered in the Australian New Zealand Clinical Trials Registry (ACTRN12618000824268).

636 **Funding**

637 The ReCEnT cohort study in which the principle element of this project is nested was funded until 2015 by the
638 participating educational organizations: General Practice Training Valley to Coast, the Victorian Metropolitan
639 Alliance, General Practice Training Tasmania, Adelaide to Outback GP Training Program, and Tropical Medical
640 Training, all of which were funded by the Australian Government. From 2016, ReCEnT is funded by an Australian
641 Department of Health commissioned research grant and supported by the GP Synergy Regional Training
642 Organisation.

643 The BENEFIT project is funded by a competitive Educational Research Grant of the Royal Australian College of
644 General Practitioners (ERG-02). GP Synergy, the Regional Training Organisation delivering general practice education
645 and training in New South Wales and the Australian Capital Territory, is delivering the educational intervention as
646 part of the GP Synergy educational program.
647 The funders had and will have no role in study design; collection, management, analysis, and interpretation of data;
648 writing of the report; and the decision to submit the report for publication.

649 **Roles and responsibilities**

650 PM is the chief investigator responsible for overall conduct of the study. PM conceived of the study. PM, SH, AD,
651 MvD coordinated design of intervention. BB provided expertise in behavior change. SH, MvD, BB, AD, AnD, MN, AT,
652 KF, NS provided methodological and clinical input into quantitative study design and analysis. MvD will provide
653 oversight of qualitative study and analysis. AT is responsible for data management and conduct of in-house
654 statistical analyses. EH is providing overall supervision of statistical analyses. MvD will provide assistance in conduct
655 of qualitative study. KP is the overall project manager. IP and DQ are responsible for day-to-day running of the
656 project, development of study and regulatory documents and construction of REDcap survey tools. All authors
657 contributed to refinement of the study protocol and approved the final manuscript.

658 The funders had and will have no role in study design; collection, management, analysis, and interpretation of data;
659 writing of the report; and the decision to submit the report for publication.

660 **Composition, roles and responsibilities of the steering committee, management team, and working group**

661 **Principal investigator**

662 Design and conduct of BENEFIT
663 Preparation of protocol and revisions
664 Preparation of study documents
665 Organising steering committee meetings
666 Managing Regulatory requirements (Ethics, ANZCTR)
667 Publication of study reports / papers

- 668 **Steering committee (SC)**
- 669 (see title page for members)
- 670 Agreement of final protocol
- 671 Recruitment of participants and liaising with RTO study sites
- 672 Reviewing progress of study and if necessary agreeing changes to the protocol to facilitate the smooth running of
- 673 the study.
- 674 **Project management committee**
- 675 Study planning
- 676 Day to day governance of project management
- 677 Organisation of SCMs
- 678 Responsible for study master file
- 679 Budget administration and contractual issues
- 680 Assistance with regulatory documents: Ethics and ANZCTR
- 681 Assistance with regulatory reporting (RACGP ERG reports)
- 682 **Project working group**
- 683 Design of educational intervention: Workshop / online module/ webinar/ Supervisor-Registrar activity
- 684 Development of questionnaires
- 685 Development of case studies
- 686 Selection/ development of supporting material
- 687 **Data manager**
- 688 Development/Maintenance of study IT system and data entry
- 689 Data verification
- 690
- 691
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877 Table 1: Theoretical framing of the BENEFIT intervention within the Behaviour Change Wheel

Sources of behaviour	Intervention functions	Intervention component	Aim	Intervention component content
Capability Motivation	Education Persuasion	Pre and post workshop resources	Increase motivation and capability to reduce prescription and initiation of benzodiazepines by changing knowledge and attitudes	Background information on the harms, addictive qualities and limited value of benzodiazepines. Evidence of benefits of reduced benzodiazepine prescribing. Non-pharmacological management of anxiety and insomnia
Capability Motivation	Education Persuasion Feedback	Face-to-face workshop (addiction specialist-led)	Increase motivation and capability to reduce prescription and initiation of benzodiazepines and to improve patient management of anxiety and insomnia through non-pharmacological methods by changing knowledge and encouraging reflection	Expert opinion on benzodiazepines and addiction. ReCENT data on registrars' prescribing and initiation of benzodiazepines will be used to contextualize and reinforce practical relevance. The 'how to' of non-pharmacological management of anxiety and insomnia within the environment of everyday general practice.
Capability Motivation Opportunity	Education Persuasion Modelling Enablement Environmental restructuring	Supervisor webinar	Increase registrar capability and motivation through empowerment	Succinct overview of harms of benzodiazepines and imperative to reduce their use in the community. Provision of potential models of supervisor-registrar collaboration and reciprocity in reducing benzodiazepine prescriptions. Discussion of processes for reducing prescriptions and improving management of anxiety and

				insomnia using non-pharmacological means.
Capability Motivation Opportunity	Education Persuasion Training Modelling Enablement Environmental restructuring	Supervisor/Registrar teaching activities	Increase registrar capacity to reduce repeat prescribing of benzodiazepines and initiation of such treatment and to improve patient management of anxiety and insomnia through non-pharmacological methods, by augmenting self-efficacy. Drive opportunities to discuss and initiate deprescribing	Registrar and supervisor encouraged to review anxiety and insomnia cases, and clinical notes. Supervisor gives registrar 'license' to manage patients without recourse to benzodiazepines. Encouraged to use non-pharmacological strategies.

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