

1 **BACK Complaints in the Elders - Chiropractic (BACE-C):**

2 **Design of a cohort study in chiropractic care**

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25

26 Figures: Figure 1

27 Tables: Table 1

28 **Abstract**

29 Background: Low back pain is a common condition among older adults that significantly influences
30 physical function and participation. Compared to their younger counterparts, there is limited information
31 available about the clinical course of low back pain in older people, in particularly those presenting for
32 chiropractic care. Improving our understanding of this patient population and the course of their low back
33 pain may provide input for studies researching safer and more effective care than is currently provided.

34 Objectives: The primary objectives are to examine the clinical course over one year of the intensity,
35 healthcare costs and improvement rates of low back pain in people 55 years and older who visit a
36 chiropractor for a new episode of low back pain.

37 Methods: An international prospective, multi-center cohort study with one-year follow-up. Chiropractic
38 practices are to be recruited in the Netherlands, Sweden, United Kingdom and Australia. Treatment will be
39 left to the discretion of the chiropractor. Inclusion/Exclusion criteria: Patients 55 years and older who are
40 accepted for care having presented to a chiropractor with a new episode of low back pain and who have not
41 been to a chiropractor in the previous six months for an episode of low back pain are to be included,
42 independent of whether or not they have seen another type of health care provider. Patients who are unable
43 to complete the web-based questionnaires because of language restrictions or those with computer literacy
44 restrictions will be excluded as well as those with cognitive disorders. In addition, those with a suspected
45 tumor, fracture, infection or any other potential red flag or condition considered to be a contraindication for
46 chiropractic care will be excluded. Data will be collected using online questionnaires at baseline, and at 2
47 and 6 weeks and at 3, 6, 9 and 12 months.

48 *Trial Registration:* Nederlandse Trial Registrar NL7507

49 *Keywords*

50 Ageing, chronic pain, epidemiology, low back pain, aged, elderly, spinal manipulation, chiropractic

51 **Background**

52 Worldwide, low back pain is the leading cause of years lived with disability and contributes to the global
53 burden of disease (1,2). Low back pain is associated with decreased mobility, reduced social participation,
54 increased isolation and difficulty with activities of daily living and thus has a negative effect on overall
55 health-related quality-of-life in older adults. Older adults with low back pain also more commonly suffer
56 from a range of co-morbidities when compared to those without low back pain (3,4). This results in large
57 costs of care, which are estimated to exceed €400 billion per year worldwide (5).

58 Low back pain is generally more severe with increasing age (6). For example, one in every four people
59 aged >80 years will report moderate to severe low back pain and people aged >80 years are three times
60 more likely to have high intensity low back pain (scores >50, on a zero to 100 scale) than those aged 50-59
61 years (7). One-fifth of older adults with low back pain report difficulties in caring for themselves at home
62 or participating in family- and social activities (8). Older people seeking care because of low back pain
63 more commonly receive treatments that have been shown to be ineffective and harmful such as opioid
64 prescription, spinal injections or surgery than younger people seeking care for low back pain (9).

65 Chiropractors provide a significant portion of care for patients with low back pain (10), and care from
66 chiropractors in the younger and older population appears to be safe and effective (16–18). Unfortunately,
67 existing trials have typically included only younger adults with low back pain, and exclude older adults for
68 various complicating reasons, such as comorbidity and polypharmacy (19-21). As a significant proportion
69 of chiropractors treat older adults (16), it is important to understand the course and characteristics of low
70 back pain in older adults under this care. Perhaps more importantly, chiropractic care may delay functional
71 decline in older adults and improve self-rated health (17,18).

72 In short, there is a general lack of knowledge regarding low back pain in older adults, but more importantly,
73 data are lacking on course of low back pain for this population in a chiropractic setting (15,19).

74 The current BACE-C consortium study has been modelled after the ‘BACK Complaints in Elders’ study
75 (BACE), which is an international cohort study devoted to examining back complaints in older people in
76 primary care (23). The BACE-C study is set in chiropractic care. The primary objectives are to examine the
77 clinical course over one year of the intensity, healthcare costs and improvement rates of low back pain in
78 people 55 years and older who visit a chiropractor for a new episode of low back pain.

79 **Methods**

80 Study design. This study is designed as an international, multi-center prospective cohort study. Data are to
81 be collected from patients 55 and older with low back pain who visit a chiropractor. Follow-up
82 measurements will be scheduled at 2 weeks, 6 weeks, 3 months, 6 months, 9 months and at one year after
83 the first treatment. Participants are to be recruited from the private practices of chiropractors in the
84 Netherlands, Sweden, Australia and the United Kingdom using the same recruitment strategies. The
85 procedures and design outlined in this paper are to be followed by the participating countries and describe
86 a common set of primary outcome measures and patient- and chiropractic factors to be measured. Care will
87 be at the discretion of the participating chiropractors. Ethics approval will be obtained in each participating
88 country prior to data collection.

89

90 *Participants*

91 Inclusion criteria: Patients aged 55 and older who consult a chiropractor for an episode of low back pain
92 regardless of duration, either for the first time or patients who have not been to a chiropractor in the previous
93 six months are to be recruited, independent of whether or not they have seen another type of health care
94 provider for the current episode. All low back complaints, with pain in the region from the thoracolumbar
95 12th rib junction to the first sacral vertebrae, including pelvic pain and pain referral to the leg(s) are to be
96 included.

97 Exclusion criteria: Patients who are unable to complete the web-based questionnaires because of language
98 restrictions or computer literacy restrictions will be excluded as well as those with cognitive disorders. In
99 addition, those with a suspected tumor, fracture, infection or any other potential red flag or condition
100 considered to be a contraindication for chiropractic care will be excluded.

101

102 *Inclusion Procedure*

103 Participating chiropractors will be asked to refer all potential participants who fulfill the inclusion criteria
104 to the online questionnaire, preferably prior to the first appointment. Participants will be briefly informed
105 about the study procedures over the phone when they call to make an appointment or during the initial
106 consultation with the chiropractor. The chiropractor or chiropractic assistant will ask for the patient's
107 permission to send an email with a link to the informed consent and baseline questionnaire, so that it can

108 be completed at home prior to the first visit or as soon as possible and no later than two weeks after the
109 initial visit. Figure 1 shows the proposed flow of patient inclusion.

110

111 *Questionnaires*

112 Links to the questionnaires will be sent by email and completed as a web-based questionnaire at baseline,
113 2 and 6 weeks, and at 3, 6, 9 and 12 months after the initial visit. In Sweden data will not be collected after
114 6 weeks because of logistical burden. Table 1 shows the measurements per follow-up round and the time
115 frame for data collection.

116 The primary outcome measures are: 1) low back pain intensity, 2) back-specific functional status and 3)
117 global perceived effect. As a secondary measure, 4) healthcare costs will be measured. All outcomes are
118 self-reported.

119 Patient-related factors: The following factors will be measured at baseline: 1) sociodemographic
120 characteristics (i.e. age, gender, marital status, education level, height, weight); 2) physical activity
121 (measured with the International Physical Activity questionnaire (20)); 3) other lifestyle variables smoking;
122 measured by pack years (21), alcohol use measured by the short version of the AUDIT-C (22,23), sleeping
123 habits; measured by the short version of the Pittsburgh Sleep Quality Index (24); 4) comorbidities using
124 the Self-administered Comorbidity Questionnaire (25) and 7) indicator screening tool (STarT Back) for
125 poor outcome (26) and 5) quality-of-life measured with the EQ-5D-5L at baseline only. In Sweden the EQ-
126 5D-3L will be used. The EQ-5D measures five dimensions: mobility, self-care, usual activities,
127 pain/discomfort and anxiety/depression (28,29).

128 In the Netherlands, each chiropractor will also perform at the first consult the “timed Up & Go” test (30).
129 The “timed Up & Go” test is composed of a variety of movements which are necessary for daily activities:
130 walking, standing up, turning, stopping, and sitting down; and predictive of falls in the elderly (30). In
131 previous studies, this test showed associations with quality-of-life scores (31).

132 Pain: Pain intensity will first be measured using an 11-point numerical rating scale (NRS) (32) in which 0
133 represents ‘no pain’ and 10 represents ‘the worst pain ever’. Second, several questions about the severity
134 and reoccurrence of complaints will be asked at all follow-up measurements (table 1).

135 Back-specific functional status: Functional status will be measured at baseline and all follow-up intervals
136 using the Roland Morris Disability Questionnaire (RMDQ) (33), in which total score can range from 0 (no
137 disabilities) to 24 (severe disabilities).

138 Global perceived effect: Global perceived effect (GPE) will be measured on a 7-point scale, ranging from
139 ‘completely recovered’ to ‘worse than ever’ (33,34). Patients will be asked to provide additional (open-
140 ended) explanation if they report worse or much worse global perceived effect compared to the previous
141 follow-up measurement. GPE will be dichotomized for the analyses as follows: ‘completely recovered’ and
142 ‘much better’ will be considered ‘improved’, while all other responses will be considered ‘not improved’
143 (35).

144 Healthcare consumption: Healthcare consumption will include the use of all primary health care (e.g.
145 general practitioner, physiotherapist), all secondary healthcare (e.g. hospital based neurologist, orthopedic
146 surgeon), hospitalization, complementary care (e.g. acupuncture, dry needling, massage) as well as the use
147 of both prescribed and over the counter medication. Questions were adapted based on the iMTA medical
148 consumption questionnaire (36). Healthcare consumption characteristics will be valued in accordance with
149 costing guidelines of each participating country, such as the Dutch Manual of Costing (37).

150 Chiropractor-related factors: These variables will be obtained from the chiropractors themselves: 1)
151 sociodemographic (age, gender), school attended (school, year of graduation), and types of treatments
152 commonly delivered in their practice.

153 In the Netherlands and in Sweden, each chiropractor will be asked to fill in several questions about their
154 expectations of patient recovery. This will be asked at the first four treatment visits.

155

156 *Statistical analyses*

157 Descriptive analyses: Baseline variables will be presented as percentages for categorical variables and as
158 means plus standard deviations for continuous variables. In case of non-normal distributions, continuous
159 variables will be described as medians with corresponding interquartile ranges. Furthermore, descriptive
160 information of the primary and secondary outcome variables will be presented for baseline and all follow-
161 up intervals. Descriptive analyses will be conducted for the entire data set from all participating countries
162 as well as stratified for each country.

163 The primary objective will be answered using the entire data set from all participating countries and
164 subsequently stratified by country.

165 In addition, the primary objective will be answered for each primary outcome separately by multilevel
166 models with three levels (observations over time clustered within patients, clustered within practices).
167 Country will be included as a covariate in the models (as dummy variables) (38). The models will thus

168 include time as a continuous variable as well as country as independent variables. Potential need for time
169 squared and time cubed will be investigated by assessing the significance level of the quadratic and/or cubic
170 terms. A random intercept will be included a priori. The need for a random slope for time will be
171 investigated by the likelihood ratio test, in a stepwise manner (38).

172 The clinical course of pain and back-specific functional status will be analyzed by linear multilevel models,
173 global perceived effect by logistic multilevel models and healthcare costs by a linear multilevel model with
174 bootstrapped confidence intervals because of the expected skewed distribution of the cost data. We will
175 report regression coefficients (linear models), odds ratios (logistic models), corresponding 95% confidence
176 intervals and two-sided p-values.

177 **Discussion**

178 This study is to our knowledge the first large-scale, prospective, multicenter, international study to be
179 conducted in a chiropractic setting and the first one focusing on older adults with low back pain consulting
180 a chiropractor. The primary objectives of the BACE-C study are to examine the clinical course over one
181 year of the intensity, healthcare costs and improvement rates of low back pain in people 55 and older who
182 visit a chiropractor for a new episode of low back pain. By understanding the impacts of various factors on
183 the course and treatment of low back pain in the elderly population, this large data set will allow us to
184 provide input for the development of future feasibility intervention studies in this patient group. We invite
185 other research groups worldwide to join the BACE-C consortium.

186

187 *Data Management, Storage and Security*

188 Data will be stored on institutional network drives with firewalls and security measures in place according
189 to national and European Union data protection regulations. Hard copy records will be stored in a locked
190 cabinet in a secure location. Access to records and data will be limited to study personnel. Study data will
191 be de-identified and a master log file with identifiers will be kept and stored separately from the data. Only
192 anonymized data will be used for analyses.

193

194 *Declarations*

195 *Ethics approval and consent to participate*

196 This protocol has received ethical approval from the Medical Ethics Committee of the Vrije University
197 Medical Center number, the Netherlands ethics number 2017-618, the Karolinska Institutet, Sweden ethics
198 number 2018/474-31/2 and the Science & Engineering Subcommittee, Human Research Ethics Committee
199 at Macquarie University, Australia, Project ID 5460. Currently the UK are awaiting ethics approval.

200 *Consent for publication*

201 Written informed consent was obtained from the patient for publication of their individual details and
202 accompanying images in this manuscript. The consent form is held by the authors' institution in a secured
203 server and is available for review by the Editor-in-Chief.

204 *Availability of Supporting Data*

205 Data sharing is not applicable to this article as no datasets were generated or analyzed during the current
206 study.

207 *Competing interests*

208 ADJ, KD and SMR work as chiropractors in private practice. MvT and SMR received grants from the
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225 *Authors' contributions*

226 Concept and design: Alan Jenks, Trynke Hoekstra, Bart Koes, Maurits van Tulder, Sidney Rubinstein
227 Drafting of this manuscript: Alan Jenks, Trynke Hoekstra, Maurits van Tulder, Sidney Rubinstein
228 Critical revision of the article for important intellectual content: All members
229 Final approval of the article: All members

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360 **Figure 1**

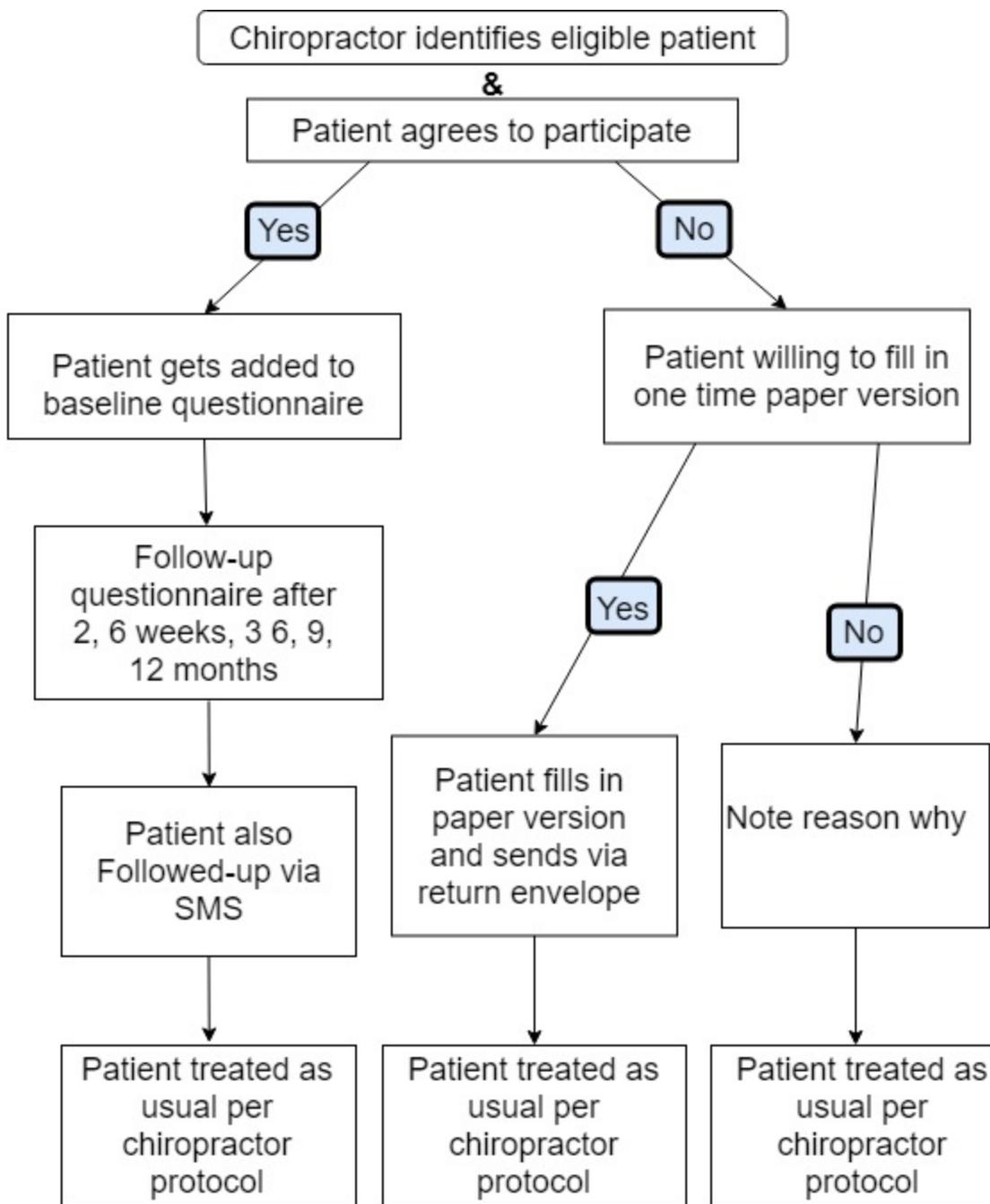


Figure 1 Flow Chart of BACE-C Study

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363 **Table 1: Content of the patient questionnaires**

Demographics	Baseline	2 weeks	6 weeks	3 months	6 months	9 months	12 months
Age	X						
Gender	X						
Ethnicity	X						
Education level	X						
Marital Status	X						
Weight (for BMI)	X						
Height (for BMI)	X						
Primary Outcome Measures							
Global Perceived Effect		X	X	X	X	X	X
Recurrence of back pain		X	X	X	X	X	X
Severity of pain (11-point numeric rating scale)	X	X	X	X	X	X	X
Roland Morris Disability Questionnaire	X	X	X	X	X	X	X
E5-Q5-DL	X						
Cost Evaluation/ Healthcare Satisfaction	X	X	X	X	X	X	X
Adverse Events to Treatment		X	X	X	X	X	X
Pain Factors							
Duration, onset of symptoms, frequency, radiation, numbness, weakness	X						
Expectations of recovery	X						
Satisfaction with the current physical condition	X						
Lifestyle Factors							
Physical activity: International Physical Activity Questionnaire	X						
Smoking	X						

AUDIT-C Questionnaire	X						
Pittsburgh Sleep Quality Index	X						
Comorbidity Questionnaire	X						
Psychosocial Factors							
STarT Back Screening Tool	X						
Physical Exam							
Get Up & Go Test	X						

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Demographics	Baseline	1 week	3 months	6 months	9 months	12 months	18 months
Age	X						
Gender	X						
Ethnicity	X						
Education level	X						
Marital Status	X						
Weight (for BMI)	X						
Height (for BMI)	X						
Primary Outcome Measures							
Global Perceived Effect		X	X	X	X	X	X
Recurrence of back pain		X	X	X	X	X	X
Severity of pain (11-point numeric rating scale)	X	X	X	X	X	X	X
Roland Morris Disability Questionnaire	X	X	X	X	X	X	X
E5-Q5-DL	X						
Cost Evaluation/ Healthcare Satisfaction	X	X	X	X	X	X	X
Adverse Events to Treatment		X	X	X	X	X	X
Pain Factors							
Duration, onset of symptoms, frequency, radiation, numbness, weakness	X						
Expectations of recovery	X						

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physical condition							
Lifestyle Factors							
Physical activity: International Physical Activity Questionnaire	X						
Smoking	X						
AUDIT-C Questionnaire	X						
Pittsburgh Sleep Quality Index	X						
Comorbidity Questionnaire	X						
Psychosocial Factors							
STarT Back Screening Tool	X						
Physical Exam							
Get Up & Go Test	X						

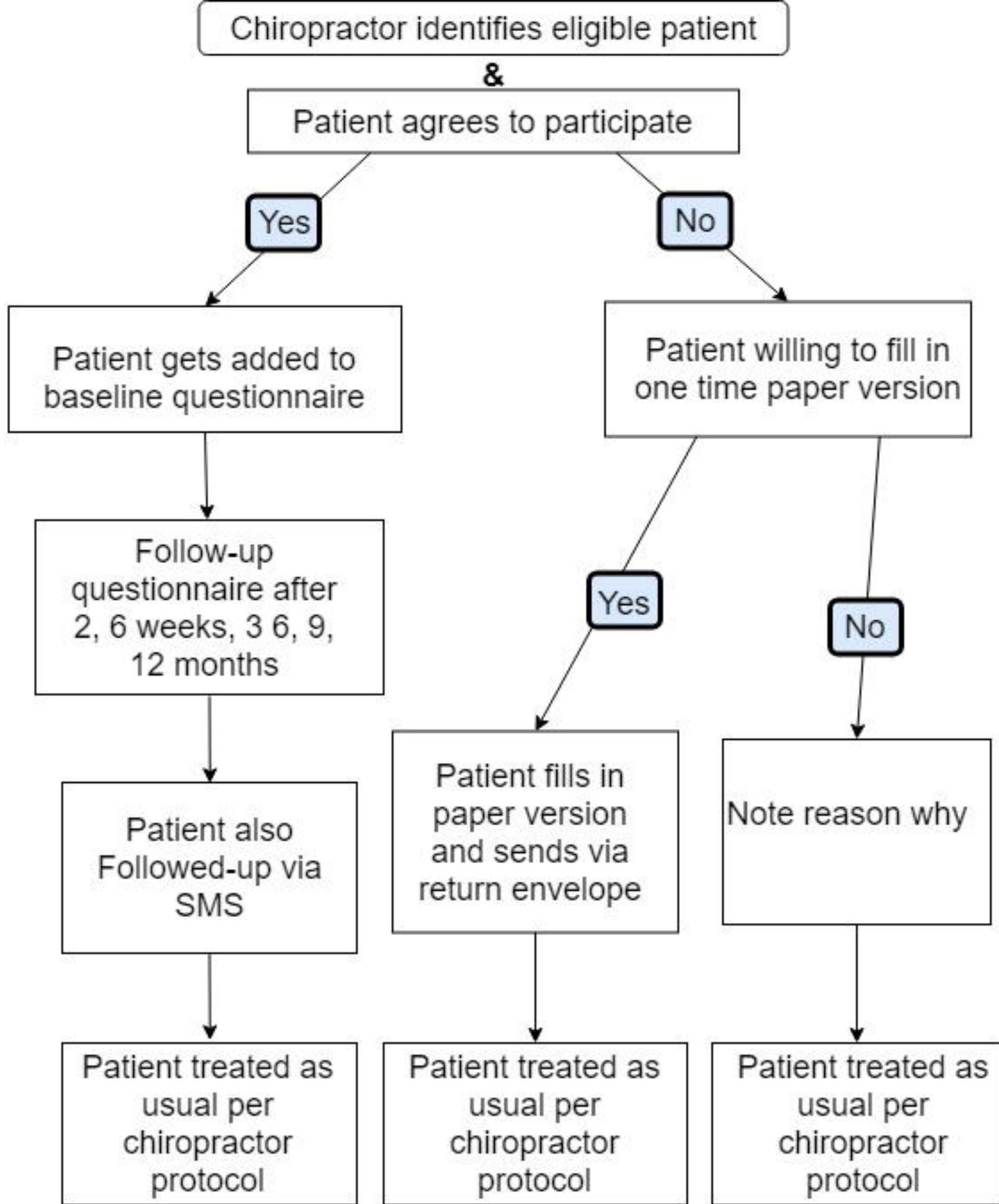


Figure 1 Flow Chart of BACE-C Study