

Attitudes towards oral health in patients with rheumatoid arthritis

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DOI:

[10.1177/2380084419833694](https://doi.org/10.1177/2380084419833694)

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Document Version

Peer reviewed version

Citation for published version (Harvard):

Serban, S, Dietrich, T, Lopez-Oliva, I, De Pablo, P, Raza, K, Filer, A, Chapple, I & Hill, K 2019, 'Attitudes towards oral health in patients with rheumatoid arthritis: a qualitative study nested within a randomized controlled trial', *JDR Clinical & Translational Research*, vol. 4, no. 4, pp. 360-370.
<https://doi.org/10.1177/2380084419833694>

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Checked for eligibility: 03/10/2019

Serban, S. et al. (2019) 'Attitudes towards Oral Health in Patients with Rheumatoid Arthritis: A Qualitative Study Nested within a Randomized Controlled Trial', *JDR Clinical & Translational Research*, 4(4), pp. 360–370. doi: 10.1177/2380084419833694. Copyright ©International & American Associations for Dental Research 2019. Reprinted by permission of SAGE Publications.

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1 **Title:** Attitudes towards oral health in patients with rheumatoid arthritis. A
2 qualitative study nested within a randomized controlled trial

3

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31 **KEY WORDS:** Periodontitis, qualitative research, patient's perspectives, feasibility
32 study, multimorbidities

33

34 **Knowledge transfer statement:** This article provided insights into the experiences
35 and perceptions of rheumatoid arthritis patients about their oral health to improve
36 patient participation in a definitive clinical trial.

37

38 **Word count:** 6552

39 Total number of tables/figures = 1 table; 2 figures

40 Number of references = 34

41 **Figures/tables legend**

42 **Table 1: Demographics of the patient population (qualitative interviews)**

43 **Figure 1: Study flow diagram**

44 **Legend Fig. 1 QEHB = Queen Elizabeth Hospital Birmingham; SWBH = Sandwell**

45 **and West Birmingham Hospitals; HEFT = Heart of England NHS Foundation Trust**

46 **Figure 2: Emerging themes from the interviews**

47

48 **Abstract**

49 INTRODUCTION: Patients with rheumatoid arthritis (RA) present higher incidence
50 and severity of periodontitis than the general population. Our study, Outcomes of
51 Periodontal Treatment in Patients with Rheumatoid Arthritis (OPERA) was a
52 randomized waiting-list-controlled trial using mixed methods. Patients randomized
53 to the intervention arm received intensive periodontal treatment and those in the
54 control arm received the same treatment with a six months delay.

55 AIM: The nested qualitative component aimed to explore patient's experiences and
56 priorities concerning oral health and barriers and facilitators for trial participation.

57 METHODS: Using purposive sampling until thematic saturation was reached, we
58 conducted 21 one-to-one semi-structured interviews with randomized patients in
59 either of the two treatment arms as well as with patients who did not consent for
60 trial participation.

61 RESULTS: The patients described their experiences about RA, oral health and
62 study participation. Previous experiences with dental care professionals shaped
63 patients' current perceptions about oral health and the place of oral health on their
64 list of priorities when compared with other conditions. Patients also highlighted
65 some of the barriers and facilitators for study participation and for compliance with
66 oral health maintenance. The patients, in the control arm, presented their views
67 regarding the acceptable length of waiting time for the intervention. CONCLUSION:
68 The associations between periodontal and systemic health are increasingly

69 recognised by the literature. Our study provided an insight into RA patients'
70 experiences and perceptions about oral health. It also highlighted some of the
71 barriers and facilitators for participating in a periodontal interventional study for this
72 group. We hope that our findings will support the design of larger interventional
73 periodontal studies in patients with rheumatoid arthritis. The complex challenges
74 faced by the burden of RA and the associated multimorbidities in this patient group
75 might highlight opportunities to improve access to oral health services in this
76 patient population.

77 **INTRODUCTION**

78 Chronic periodontitis is a very common chronic inflammatory condition. It affects
79 nearly half of the UK adult population and over 60% of the elderly (Chapple 2014;
80 White et al. 2012). Several observational studies have reported an association
81 between chronic periodontitis and rheumatoid arthritis (RA) and chronic
82 periodontitis has been suggested as a potential risk factor for RA (de Pablo et al.
83 2009; Konig et al. 2016; Mikuls et al. 2009; Okada et al. 2013; Ribeiro et al. 2005).
84 Given the high prevalence of chronic periodontitis, this association could have
85 significant clinical and public health implications.

86 The first symptoms of RA are noticed usually between the age of 35 and 50 and it
87 affects mostly women. Within 5 years of diagnosis, 40% of patients reduce their
88 working week from full time to part time, with an increase to 50% at 10 years from
89 the first diagnosis (Mathers and Pflieger 2006). Rheumatoid arthritis affects
90 patients' personal and professional relationships transforming their daily routines
91 and quality of life. Often they have to change their working circumstances or retire
92 early, adapt their living conditions, rely on help from external sources (family,
93 friends or social workers) and increase their feeling of vulnerability which is added
94 as a psychological burden to their condition (Lapsley 2002).

95 Besides the direct impact of RA on patients' quality of life, it is important to
96 consider also the indirect impact caused by the comorbidities secondary to RA and
97 the side effects of the long-term use of polypharmacy in this patient group.

98 RA has been frequently associated with other conditions including depression,
99 elevated blood pressure, cardiovascular disease and respiratory conditions.
100 (Dougados et al. 2014).

101 There are several potential mechanisms linking RA and periodontal disease. Some
102 studies have suggested that bacteraemia caused by periodontal pathogens could
103 be an etiological agent for RA progression (Martinez-Martinez et al. 2009).

104 Another widely supported model relates to an aberrant immune response to
105 periodontal pathogens in certain susceptible individuals. One of the main
106 periodontal pathogens is *Porphyromonas gingivalis*. With the recent recognition of
107 the importance of anti-citrullinated protein antibodies (ACPA) in RA and the
108 discovery that *P. gingivalis* expresses peptidyl arginine deiminase which is
109 responsible for the post-translational citrullination of peptide antigens on arginine
110 residues (Rosenstein et al. 2004), there is potential evidence to support a plausible
111 pathobiologic mechanism by which periodontitis may cause or sustain the ACPA
112 response in RA.

113 Recent studies have also demonstrated that the uncitrullinated peptides play a
114 major role in the antibody response for periodontitis resulting in a systemic spread
115 of citrullinated epitopes in the presymptomatic phase of RA. Autoantigens modified
116 by citrullination through exposure to periodontal pathogens might sustain synovial
117 inflammation in the context of untreated periodontitis (Lopez-Oliva et al. 2018;
118 Rosenstein et al. 2004). Antibodies for uncitrullinated RA autoantigens precede the
119 ACPA formation and facilitate the loss of tolerance to uncitrullinated peptides (de
120 Pablo et al. 2013).

121 Treatment of chronic periodontitis involves control of the dental biofilm, typically
122 using non-pharmacological means. Whether or not such treatment can reduce the
123 incidence and severity of RA is unknown. However, a small number of
124 interventional studies have reported encouraging results in terms of reduced RA
125 disease activity following periodontal treatment (Al-Katma et al. 2007; Okada et al.
126 2011; Ortiz et al. 2009).

127 Our trial, Outcomes of Periodontal Treatment in Patients with Rheumatoid Arthritis
128 – OPERA, was a randomized waiting list controlled feasibility study. This trial
129 provides feasibility data for a larger, multi-centre randomized controlled trial, which
130 would investigate the efficacy of non-surgical periodontal treatment in reducing
131 disease activity in patients with RA.

132 Our trial focussed on issues of recruitment and retention, acceptability and
133 feasibility of the trial procedures including the intervention, assessments and data
134 collection, using a mixed methods approach. The quantitative component of our
135 trial gathered pilot clinical data about the efficacy of periodontal treatment in
136 patients with RA and subsequently its influence on health-related quality of life.

137 Considering the severe burden that RA can have on the patient's quality of life,
138 both directly and through the comorbidities associated with this condition, it is
139 important to gain a better understanding of patients' priorities with regards to
140 accessing different types of health care services. Additionally, it is important to
141 ensure that the design of any interventional studies would take this into account
142 and patients' trial participation would not create an additional burden on their
143 quality of life. As successful periodontal treatment is heavily dependent on

144 compliance and adherence and the treatment and trial participation both require
145 multiple visits to the secondary care setting where this treatment was being
146 delivered we considered important to explore the barriers and facilitators for study
147 participation in this patient group.

148 Furthermore, in order to encourage recruitment and retention rates in the trial, it is
149 important to consider that outcomes that are relevant for clinicians and researchers
150 might be less relevant for the patients. This could be especially the case for RA
151 patients with multimorbidities as suggested in the literature (Cohen et al. 2004;
152 Fleischmann et al. 2016). Understanding the health care priorities of this specific
153 patient population and the place of oral health on their list of priorities was one of
154 the most important objectives of the qualitative component of our study.

155 Our study used a mixed method approach with a quantitative and a nested
156 qualitative component. The quantitative aspects of the trial will be presented in
157 detail in a separate paper. This paper focuses on the nested qualitative component
158 of this study.

159 **Aims and objectives**

160 The aim of the qualitative component of our study was to evaluate patients'
161 experiences, values and priorities that shape their choices in accessing oral health
162 services and identify the barriers and facilitators for participation in a randomized
163 controlled trial. In order to meet this aim, we developed the following objectives: 1.
164 Understand the impact of RA on the patient's quality of life and the place that oral
165 health occupies on their scale of health priorities; 2. Identify barriers and facilitators

166 for study participation; 3. Understand RA patients' views about randomisation to
167 the intervention or control group (delayed intervention).

168 **METHODS**

169 The OPERA trial recruited patients with RA, fulfilling the revised 1987 ACR
170 classification criteria for RA (Aletaha et al. 2010). The recruitment sites were the
171 outpatient rheumatology clinics of the Queen Elizabeth Hospital (QE), City Hospital
172 and Heartlands Hospital all in Birmingham, U.K.

173 A total of 691 RA patients were identified as potential participants from the three
174 recruitment sites. Of these, 118 declined participation in the trial predominantly due
175 to the severity of their comorbidities and the numerous medical appointments that
176 they already have to attend.

177 Of these, 296 patients consented to participate in the trial and 201 attended the
178 periodontal screening visit at Birmingham Dental Hospital. Of these, 60 met both
179 the RA and periodontal criteria for randomization and were allocated to either
180 immediate intervention or waiting list control (delayed intervention) group (Figure
181 1). The intervention consisted of non-surgical periodontal therapy delivered by a
182 dental hygienist in two or more sessions in a secondary care setting.

183 **PLEASE INSERT FIGURE 1**

184 **Study oversight**

185 Ethical approval for the OPERA trial was granted (11/WM/0235, protocol number
186 RG_10-138 and registered via the Integrated Research Application System (IRAS)
187 with project ID 53163.

188 **Recruitment**

189 The recruitment for the trial started in January 2014 and data collection ended in
190 December 2016. Research and development (R&D) approval was obtained for all
191 the participating sites.

192 Some of the inclusion criteria for the periodontal screening were, among others,
193 fulfilment of 2010 ACR/ EULAR classification criteria of RA (Aletaha et al. 2010)
194 and stable medication. For randomization, patients had to have a disease activity
195 score (DAS28) of at least 3.2 and generalized moderate to severe chronic
196 periodontitis as evidenced by pocketing with clinical attachment loss (clinical
197 attachment loss \geq 4 mm on at least 2 non-adjacent teeth and cumulative probing
198 depth \geq 40mm).

199 For exclusion criteria, we considered history of, or current, inflammatory joint
200 disease other than RA (including, but not limited to, gout, reactive arthritis, psoriatic
201 arthritis, seronegative spondyloarthropathy); any surgical procedure including
202 bone/joint surgery/synovectomy (including joint fusion or replacement) within 12
203 weeks prior to baseline or planned during study and periodontal treatment within
204 12 months prior to baseline.

205 A detailed description of the clinical methodology and findings will be reported in a
206 separate paper.

207 **Screening**

208 Patients were approached for consent during their rheumatology follow-up
209 appointments at the participating hospitals. After consenting, clinical rheumatologic

210 data were collected and a screening appointment was offered at the OPERA
211 research clinic at Birmingham Dental Hospital. As some patients expressed an
212 unwillingness to participate because of the logistic difficulties in getting to the
213 Dental Hospital, further assistance was offered with transportation to these
214 patients. Reminder letters with the appointment date and time for the Screening
215 visit were sent out by post to each newly booked patient. One or two days before
216 the appointment, a research nurse called the patients to remind them of their
217 appointment.

218 At Birmingham Dental Hospital, patients were assessed in a dedicated clinic
219 available for OPERA trial patients. This involved general clinical examination,
220 rheumatologic assessment including the disease activity score 28 (DAS28), full
221 mouth probing, and biological sample collection.

222 **Randomization and follow-up**

223 If patients fulfilled the eligibility criteria for randomization and treatment, they were
224 offered participation in the interventional phase of the study. After consenting for
225 randomization and treatment, patients were randomly allocated to either immediate
226 treatment or delayed treatment (waiting list control). For the patients allocated to
227 the immediate treatment arm, three appointments were booked with a dental
228 hygienist allocated for this project at maximum of three weeks after the Screening
229 visit. Patients in the delayed treatment arm had one appointment with the same
230 hygienist for instructions on oral health maintenance.

231 The same clinical examinations were carried out at the follow-up visits as at
232 baseline. The patients allocated to the delayed treatment group were offered three
233 appointments with the same dental hygienist for periodontal treatment at the end of
234 the study. All the patients, at the end of the study received £150 to cover the
235 possible costs regarding their commitments for study participation. Most patients
236 who did not wish to consent for screening were offered the possibility to participate
237 in the qualitative interview process, either face to face or over the telephone.
238 Inviting patients who did not consent to take part in the clinical trial to participate in
239 the qualitative interviews was particularly important to meet our aims and
240 objectives in identifying barriers and facilitators for study participation.

241 **Sample Selection**

242 For the purposes of the qualitative component of this study, we used a purposeful
243 sampling technique aimed to include a variety of patients and to ensure broad
244 representation of views relevant to the various aspects of study participation. We
245 therefore invited patients who:

- 246 • Had declined to consent for the clinical intervention
- 247 • Were screened but were not eligible for randomization for the clinical
248 intervention
- 249 • Were randomized to the immediate periodontal treatment group
- 250 • Were randomized to the control group
- 251 • Were representing gender diversity
- 252 • Presented different lengths of time since diagnosis (RA)

253 One to one, semi-structured interviews were conducted with patients from all these
254 groups until thematic saturation was reached. As new themes emerged from the
255 discussions, the topic guide was constantly adapted and new themes were added
256 until saturation was reached. Saturation was defined as the stage at which no new
257 themes emerged from the interviews and the data started to become mainly
258 repetitive. After saturation, three more interviews were conducted for quality
259 assurance purposes. All interviews were carried out by the same researcher to
260 ensure consistency. All interviews were recorded and fully transcribed. The first
261 five interviews were conducted by a dentist under the supervision of an expert in
262 qualitative research (psychologist). The interviews were conducted at Birmingham
263 Dental Hospital, Queen Elizabeth Hospital Birmingham and over the telephone
264 between October 2014 and January 2016 and lasted on average 30 minutes.
265 Sixteen interviews were conducted face to face and five over the telephone. Some
266 participants preferred to have the interview conducted over the telephone for
267 convenience, especially those who did not wish to consent for trial participation. In
268 relation to the other aspects of the study, the first patient was screened in February
269 2014 and the last patient was randomized in October 2015.

270 **Topic guide**

271 The initial topic guide developed by the research team included: oral health
272 maintenance, treatment preferences (dental and medical), access to dental care,
273 priorities and values placed on oral health, quality of life issues, acceptability of the
274 periodontal treatment and, if applicable, reasons for non-participation. This initial

275 topic guide was piloted with three patients who consented to participate. The
276 piloting phase was developed and implemented by the research team to ensure
277 methodological accuracy of the interview process. The results of these three
278 interviews were included in the overall findings. Based on the dynamics of the
279 discussions and the flexible structure of the interviews, new themes emerged that
280 were incorporated in the topic guide and added to the interviews with subsequent
281 participants.

282 **Data analysis and validation**

283 A framework approach to data analysis was adopted in the manner suggested by
284 Pope et al. (Pope and Mays 2006). The framework was developed using the topic
285 guide and additional columns were added to the framework as new themes
286 emerged from the interviews. One researcher (dentist) carried out the interviews
287 and the analysis in order to assure consistency and robustness. The transcripts
288 were read and analysed independently by a second researcher (psychologist)
289 following NICE guidelines (Tan et al. 2009). The two researchers discussed and
290 reached consensus of the findings. A third independent researcher was available
291 to oversee the findings in case a consensus was not reached.

292 **RESULTS**

293 **Patient demographics**

294 21 participants (15 females, 6 males) with a median age of 60 years were
295 interviewed to participate in the interviews (Table 1).

296 RA disease duration ranged from 1 year to 60 years (median 19 years). More than
 297 half of the participants (n=13) had consented for periodontal screening in the study,
 298 while the remaining participants did not (n=8) (Table 1).

299 Table 1 Demographic characteristics of participants in the qualitative component

Pt #	Gender	Age	Years since diagnosis	Patient group
1	F	60	19	Randomized - delayed
2	M	86	20	Refused trial participation
3	F	83	60	Refused trial participation
4	F	37	9	Refused trial participation
5	M	52	13	Randomized - delayed
6	F	59	20	Refused trial participation
7	F	68	22	Refused trial participation
8	M	65	30	Randomized - delayed
9	F	60	67	Refused trial participation
10	F	65	6	Randomized - delayed
11	F	55	12	Randomized - immediate
12	F	59	2	Refused trial participation
13	M	54	14	Refused trial participation
14	M	64	10	Not eligible for randomization
15	F	62	36	Randomized - delayed
16	F	47	15	Randomized - delayed
17	F	61	15	Randomized - delayed
18	F	62	25	Randomized - immediate
19	F	62	30	Randomized - delayed
20	M	57	20	Randomized - immediate
21	F	57	1	Randomized - immediate
Median [IQR]		60 [57,64]	19 [12,25]	

300

301 The main emerging themes from the framework analysis are presented in Figure 2.

302 These can be clustered into three main areas: “RA and quality of life”, “Oral health”

303 and “The Study”. The new topics that emerged from the discussions were related

304 to patients’ perceptions of oral health and their previous experience with dental

305 care professionals. Furthermore, the patients elaborated on their health priorities,

306 perceived barriers for study participation and potential solutions for the removal of
307 those barriers.

308 **PLEASE INSERT FIGURE 2**

309 **Rheumatoid arthritis and quality of life**

310 Discussions started with participants describing their experiences regarding the
311 onset and subsequent history of their RA and the effect it had on their quality of
312 life. All participants described the onset of their condition as highly distressing.

313 *"I remember going to pick my son up from school and walking up the high*
314 *street and just with tears rolling down my face because I was in such pain...*
315 *I had never known anything like it and then it just got worse from there...*
316 *Everyday things that I would have done without blinking an eye just became*
317 *totally impossible to do because I had no grip in my hands, no strength then*
318 *to actually get myself up in the bed."* (P1)

319 Each story carried a vivid and painful memory associated with anxiety and distress
320 as patients and their families struggled to understand what was happening:

321 *"The children thought I was going to die. I heard them talking to my wife*
322 *and they said "Is dad going to die?" and I thought, blimey, I must look bad,*
323 *but I was so thin me bones were sticking out all over the place."* (P14)

324 Some of the patients shared their stories about the impact that RA had on their
325 work and socio-economic status. In some cases, this went as far as the patients
326 having to change their living arrangements and make compromises in order to find
327 ways to adapt to their new situation.

328 *“I did retire early yes as a consequence and I had to give my home up*
329 *because I couldn’t get up the stairs any more... So, within a very short*
330 *space of time from 2010 to 2014 I retired early and I lost my home... I*
331 *am living in a bungalow now, which has been adapted for my needs. I’ve*
332 *got a wet room as opposed to a bathroom.” (P10)*

333 The majority of patients mentioned that they had taken early retirement or had to
334 reduce their work schedule from full-time to part-time because of the impact of RA
335 on their work life. Patients reported that this had a major negative impact on their
336 socio-economic status.

337 Besides work, RA also affected the ability of patients to enjoy their hobbies and
338 social activities.

339 *“I used to enjoy football, fishing, things like that. I couldn’t go fishing cos*
340 *I couldn’t hold the rod any longer in that one position holding the rod.”*
341 *(P20)*

342 As the discussions developed around the traumatizing experiences caused by the
343 onset of RA, the patients started to describe also the challenges represented by
344 several comorbidities that they had to deal with.

345 **Comorbidities and health priorities**

346 As the average age of the participants was around sixty years, comorbidities
347 associated with RA were common. In order to gain a better insight into the reasons
348 why they might or might not participate in the study, it was important to understand
349 their health care priorities and the impact of their comorbidities and how they

350 prioritize the health care services that they are accessing. Another factor was to
351 understand where oral health was situated on their list of health care priorities.

352 Although, several patients declared oral health as a priority in the beginning of the
353 interview, as the discussions evolved and they reported on comorbidities, they
354 presented a tendency to prioritise other comorbidities compared to oral health:

355 *“So, I have rheumatoid arthritis and I have asthma/COPD, so I have*
356 *breathing problems, but again somebody is looking after me... And that is*
357 *linked to what used to be a constant round of chest infections, but they now*
358 *seem to have this under control and then oral health is the third most*
359 *important thing in my life.” (P9)*

360 Patients’ numerous different hospital appointments represent a burden to some of
361 the patients and the dental care occasionally tends to become less of a priority:

362 *“No, no I probably haven’t been to the dentist, it has got to be a year now,*
363 *so but part of that is that I have so many appointments for different things at*
364 *the moment, that unless I am reminded of an appointment, or given an*
365 *appointment they tend to slip away.” (P5)*

366 As most of the patients had multiple comorbidities, some of them tended to place
367 oral health as the last one on the scale of importance. Their main priorities were
368 systemic conditions including RA itself, cardiovascular disease, Crohn’s disease,
369 asthma, chronic obstructive pulmonary disease (COPD), diabetes, etc.

370 *“My chest really, my chest is first then my rheumatoid. My teeth, round*
371 *about third I think to be honest.” (P7)*

372 *"But the other thing to remember is for patients like me who have got*
373 *rheumatoid, they've probably got other ongoing conditions as well. There is*
374 *so many things you have to try and focus on." (P4)*

375 In light of these, some patients reported that they would prefer to have their teeth
376 extracted rather than have multiple appointments for conservative treatment:

377 *"If I had to have teeth out, I have to have them out and that's the end of it."*
378 *(P4)*

379 **Periodontitis and oral health**

380 Discussions focused on patients' perceptions about oral health, their self-reported
381 oral health status and previous experience that they had had with dental care
382 professionals. Few participants reported having a good oral health status. Their
383 past experiences regarding oral health care services shaped their perception
384 regarding their current behaviour for accessing oral health services:

385 *"Then you never used to go to the dentist, they used to come around the*
386 *school, this is going back a long time nineteen fifties and sixties. ... And*
387 *then most of the time they just pulled your teeth out. That was, they never*
388 *did any fillings or anything they just looked at your teeth and if they didn't*
389 *like the look of it, they just pulled out your teeth." (P14)*

390 Patients acknowledged the importance of good oral health and reported making
391 efforts to try to help their children to maintain good oral health:

392 *"I mean my kids so soon as they were old enough, like two or three, I would*
393 *take them, we would take them to a dentist just to get them used to a*
394 *dentist, because I think fear of dentists..." (P14)*

395 Many patients reported that maintaining their oral hygiene was more difficult on the
396 days with flare-ups:

397 *"If I have a bad flare-up of arthritis, I can't ... and I miss it and I am not able,*
398 *I don't have the strength to hold my electric toothbrush, because it is quite*
399 *heavy" (P9)*

400 *"If my shoulder hurts then it's ... it can be a bit difficult to brush." (P13)*

401 Even holding the toothbrush could be challenging for some patients:

402 *"I could about hold it, I haven't got many teeth left anyway. It's my fear is*
403 *dentists." (P2)*

404 Participants mentioned the importance of developing a relationship based on trust
405 with their dental care provider. This played an important role in their attitudes
406 towards oral health and their behaviours in seeking oral health care services:

407 *"Well I am concerned that my dentist hasn't done what needed to be done to*
408 *save my teeth from breaking." (P13)*

409 Respondents reported being afraid of needles and consequently being afraid of
410 dentists. Some patients stated that they would prefer to have extractions instead of
411 restorative treatments.

412 *"I suppose out would be the best at my age I suppose out, you know." (P2)*

413 When participants were asked about the way, they felt regarding their oral health,
414 and how they regarded the visit to their dentist, many patients (particularly the

415 more elderly) reported negative attitudes. Younger patients on the other hand
416 reported that they would prefer to keep their natural teeth and have them treated.

417 As the discussions continued and patients described their comorbidities secondary
418 to RA and how oral health fitted on their list of health care priorities, they also
419 expressed their views regarding the outcomes that matter the most for them with
420 regards to their quality of life and wellbeing. Amongst the most important health
421 related outcomes considered by the patients were autonomy, mobility and lack of
422 pain.

423 One of them mentioned how she needed to plan her everyday activities depending
424 on whether or not she had a flare-up:

425 *“You know, where before I used to think nothing of it, I would go off and do*
426 *what I needed to do. Now, I can’t do that, if I’m in pain I have think right I*
427 *can only do one shop today, or I can’t walk that far today.” (P12)*

428 Other stories were similar:

429 *“Health, mobility that’s very important to me that my feet were not as*
430 *compromised as my hands. Oh, that is very, absolutely I would tie those*
431 *two together.” (P3)*

432 *“The difficulty I was facing whilst I was working was the inability to hold a*
433 *pen properly And work and a computer. Erm, sitting down meant that*
434 *my joints got really stiff, my knee joints and my back. And my feet and as a*
435 *consequence mobility as I say became very bad... I couldn’t get upstairs to*
436 *the upstairs offices.” (P10)*

437 Personal mobility and the ability to keep their independence were key priorities for
438 this patient population. This was also highlighted through the potential barriers that
439 hindered study participation.

440 **Barriers for study participation**

441 The interviews explored the reasons why some patients would be reluctant to
442 participate in the OPERA study to identify potential barriers that could be
443 addressed by the research team. Several patients reported having negative
444 experiences with dentists in the past and this discouraged them to participate in
445 our trial –

446 *“Yeah, I, I think I woke up under the gas. And, I was there was blood all over*
447 *the place and I was only about this high. At school. And I never went again. I*
448 *stopped going for a long time” (P20)*

449 The location of the Dental Hospital was mentioned as a hindering factor by several
450 patients:

451 *“That was because it was the Dental Hospital and I find it difficult to get from*
452 *my part of the town to the Dental Hospital.” (P2)*

453 *“It is a bit far away, you know the other side of town but they are moving to a*
454 *new hospital shortly which will be more accessible, yes.” (P18)*

455 Due to classic features of RA such as mobility problems, fatigue and morning
456 stiffness as well as logistic issues with the traffic from their homes to the location of
457 the Dental Hospital, they found that without help, they could not attend their clinical
458 appointments.

459 Besides the location of the Dental Hospital, patients mentioned forgetfulness and
460 the overlap of their dental appointment with other medical appointments as being
461 important hindering factors for study participation.

462 **Removal of barriers**

463 In order to address these, the participants were asked to suggest potential
464 solutions for these problems. Some of the hindering factors were addressed by the
465 research team, as described in the methodology section: patients received phone
466 call reminders about their appointments and those patients that required
467 assistance for getting to the Dental Hospital, received support in arranging the
468 travel logistics around getting to their appointments.

469 *"Because as I say I wouldn't have been able to undertake the study unless*
470 *I'd have had payment for transportation." (P10)*

471 Financial incentives were set in place to compensate for the loss of time and
472 logistics for the research and treatment visits. As all patients are unique and so is
473 their situation and their experiences, some patients did not feel that financial
474 incentives should encourage patients study participation:

475 *That always seems to help I did a lot of groups and the financial side of it*
476 *isn't a big thing to me. When I did the conferences, it was all about*
477 *expenses I was happy for my expenses to be paid, but a lot of the groups I*
478 *also did erm, it would be like an interview, but there would be ten of us and*
479 *we would sit around and the discussion would be recorded and you usually*
480 *found that all those groups would be full because people were getting*

481 *financial.... they were being paid for it basically, but you would find that they*
482 *were all full, all of them.” (P5)*

483 Some patients reported that they suffered from dental anxiety and indicated that
484 the only way they would participate in the study would be if the screening and
485 treatment would be done under general anaesthesia:

486 *“I mean I did say to my son because he keeps telling me off he says, “Mom,*
487 *you really need to go and get your teeth sorted... And I said, I will go if they*
488 *can put me to sleep”. If they can knock me out.... Yeah. I said that’s the only*
489 *way I would have it done.” (P12)*

490 **The control arm**

491 The control arm in our study received the same treatment as the intervention group
492 but with a delay of six months. Patients had very diverse views with regards to the
493 how long it was acceptable to delay their treatment. Some of them preferred to
494 have no delay at all and some were happy with a delay of up to a few years.

495 One of the patients who declined trial participation considered that treatment
496 should be delivered immediately without any delay:

497 *“I think it should be done straightaway...I don’t think you should wait*
498 *because with your mouth everything that goes in your stomach goes into*
499 *your mouth so your gums are one of the main ones really aren’t they? So, I*
500 *think you know, it should be earlier than six months.” (P6)*

501 The majority of patients, however, felt that a delay of six months to their treatment
502 would be acceptable whilst more than that might influence them to seek treatment
503 elsewhere.

504 *“Oh, I think it’s six months... Six months would be alright...Well, perhaps 12*
505 *months is, I’m 84 don’t forget.” (P2)*

506 This view was shared by the majority of patients:

507 *“I was hoping not to be in the delayed group, but as I am in the delayed*
508 *group then I leave it to you erm to help me as best you can... I wouldn’t like*
509 *the longer waiting time.” (P15)*

510 **The intervention**

511 All patients who received the intervention, both in the immediate treatment group
512 as well as in the delayed treatment group reported having a positive experience
513 concerning to the intervention.

514 *“I’m really pleased actually that erm doing this study because erm had it not*
515 *been for that, this could have gone on and on and it might have got to a*
516 *really bad situation with my gums and I wouldn’t have known so I am really*
517 *pleased.” (P11)*

518 They highlighted the importance of being kept informed about the progression of
519 the study and the protocol and having pleasant interactions with the research staff

520 *Yeah, they have been good, I think the experience has been good. You*
521 *staff have been really helpful and I am aware of what is happening every*
522 *time I come and see you. The hygienist was great, she explained what she*

523 *was going to do and what she expected to do in future, so I think it has been*
524 *a really good experience as well and eye opening as well. " (P5)*

525 This view was shared by all the patients who received the intervention:

526 *"She made me feel so comfortable and it's embarrassing as well when you*
527 *go to dentist... I find I get embarrassed. And because of the state of my*
528 *teeth. I didn't feel at bit like that from the moment. I met the hygienist and I*
529 *felt quite confident that she was confident. She knew what she was doing.*
530 *She explained everything. And she told me if anything hurt or to stop, to*
531 *stop her. I just felt so comfortable with her... I would do it all over again."*
532 *(P21)*

533 **Discussion**

534 Most studies investigating the associations between periodontitis and RA have
535 used quantitative methodologies (Al-Katma et al. 2007; Pinho Mde et al. 2009;
536 Ribeiro et al. 2005). OPERA was a mixed methods feasibility study with a nested
537 qualitative component. We aimed to explore the acceptability of our study protocol
538 and understand RA patients' experiences and perspectives about accessing oral
539 health care services. Furthermore, we gained some valuable insights into the place
540 of oral health on their list of priorities, identified barriers and facilitators for study
541 participation and gathered patients' views about the intervention and about being
542 randomized to the control arm.

543 A large amount of the data regarding the oral health status of older people in
544 England is generated from surveys of people living in residential and nursing care

545 homes. This represents only a minority of the elderly population and has led to a
546 gap in our knowledge and understanding of the dental treatment preferences of
547 this age group (Public Health England 2015). Some data suggests that for some of
548 the older patients aesthetics are less of a priority and comfort and lack of pain are
549 considered more important (Lord et al. 2015).

550 To our knowledge, our study is the first one to look at oral health preferences in
551 patients with rheumatoid arthritis and at barriers and facilitators for participation in
552 a dental trial for this patient group.

553 Our sample was diverse and we purposefully included patients from all the
554 possible groups involved in the study: 1. Those who declined trial participation; 2.
555 Those who were found ineligible for randomization after screening; 3. Patients who
556 were randomized to intervention arm and 4. Patients randomized to control arm.
557 We also aimed to include patients of both genders and with different durations of
558 RA diagnosis.

559 We have found that patients' prior experiences, values and priorities tend to have a
560 strong impact on shaping their choices for accessing different health care services.
561 RA patients' treatments require a holistic approach and whilst their rheumatologic
562 care often takes into account their different systemic comorbidities, oral health is
563 commonly missed out from this picture. Patients identified a set of barriers and
564 facilitators that can influence their participation in an interventional study. Some of
565 these barriers were related to patients' limited mobility and logistic difficulties
566 associated with getting to their dental appointments.

567 Our patients' main concerns appeared to be represented by the ability to have as
568 "normal" a life as possible - to live independently, autonomously and pain free.
569 These findings are in line with the literature with regards to RA patients with
570 multimorbidities and how these shape their choices and priorities in terms of
571 accessing health care services (Malm et al. 2017; Ward et al. 2007).

572 Our patients described their personal experiences regarding RA and the impact of
573 this condition on their quality of life. They reported how the condition affected their
574 physical and emotional well-being as well as the influence it had over their socio-
575 economic status as a consequence of the reduction of work and/or early retirement
576 based on disability.

577 Although many participants acknowledged the importance of good oral health and
578 its potential impact on general health, when compared to RA and the other
579 comorbidities that they have to live with, oral health was not a high priority.

580 The patients identified a number of hindering factors that might impact on their
581 ability for study participation and some of these factors were addressed by the
582 research team with adaptations of the study protocol.

583 In many cases, patients reported that they had to balance their life around the
584 treatment they received for RA and for their comorbidities: this involved multiple
585 medications, hospital visits, etc. The overall burden of RA and of the associated
586 comorbidities over the quality of life of these patients could be quite overwhelming.

587 Compliance with regular oral hygiene maintenance is key to maintaining good oral
588 and periodontal health but it can become an extra burden for this cohort, especially
589 on the days when they are dealing with flare-ups caused by their rheumatoid

590 condition. Patients who struggle with high burden of debilitating systemic
591 multimorbidities, perhaps unsurprisingly, reported that oral health was a not key
592 priority for them.

593 We have also identified a number of limitations to this study. This cohort presented
594 a median disease duration of 19 [12, 25] years. We acknowledge that the initial
595 therapeutic options and approaches at the time of their diagnosis were quite
596 different from those of today. Therefore, we can hypothesise that disease
597 progression in this cohort could be significantly different compared to a cohort with
598 a more recent onset of RA. This could potentially lead to different findings in a
599 cohort with current early RA. When we developed the protocol for the randomized
600 controlled trial, we aimed to include patients diagnosed with RA who were on
601 stable treatment with disease-modifying antirheumatic drugs (DMARDs) for at least
602 2 months in order to reduce the likelihood of potential confounding factors caused
603 by medication changes. It is often the case for early diagnosed RA patients to
604 change classes of drugs and dosages, therefore after discussing this issue with
605 rheumatologists in the research team we decided that in order to meet this goal we
606 focus the recruitment on patients with stable established RA.

607 From a public health perspective, the burden of non-communicable diseases
608 (NCDs) is becoming more and more pressing on the limited resources available for
609 national health systems. It is perhaps time to consider new, creative ways of
610 developing care packages that may include oral health care for patients with
611 NCDs. This idea is supported by the American Diabetes Association as well as by
612 the French National Authority for Health, which recommends the inclusion of a

613 comprehensive periodontal examination as part of the referrals for initial care
614 management in diabetic patients (American Diabetes Association 2018; Haute
615 Autorité de Santé 2014). A similar approach may have beneficial effects for
616 patients with other NCDs such as rheumatoid arthritis, cardiovascular disease,
617 kidney disease, etc.

618 The nested qualitative component of the OPERA trial provided an insight into
619 rheumatoid arthritis patients' experiences and perceptions with regards to oral
620 health. Our study also highlighted some of the potential barriers and facilitators for
621 participating in a periodontal interventional study in this patient population. We
622 hope that these findings will support the design of larger interventional periodontal
623 studies in patients with rheumatoid arthritis.

624

625 **ACKNOWLEDGEMENTS**

626 Sources of Funding: This paper presents independent research partially funded by the
627 National Institute for Health Research (NIHR) under its Research for Patient Benefit
628 (RfPB) Programme (Grant Reference Number PB-PG-0609-19100).

629 SS was supported by European Union FP7-PEOPLE funded ITN project (project number:
630 RAPID – 290246).

631 KR and AF are supported by the National Institute for Health Research (NIHR)
632 Birmingham Biomedical Research Centre.

633 PP is supported by an NIHR fellowship (Grant Code: NIHR PDF-2014-07-055).

634 The views expressed are those of the authors and not necessarily those of the NHS, the
635 NIHR or the Department of Health.

636 Conflict of interest: None

637

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