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Influencing Factors Regarding Self-monitoring in Patients with Inflammatory Rheumatic Diseases

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Manuscripts

L. Renskers, S.A.A. Rongen-van Dartel, A.M.P. Huis, and P.L.C.M. van Riel

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35 **Abstract**

36 Objectives. Self-monitoring is a relatively new concept in the management of patients with

37 Inflammatory Rheumatic Diseases (IRDs), which can be done by patients by completing Patient-

38 Reported Outcome Measures (PROMs). The aim of this pilot study was to obtain patients' experiences

39 with online self-monitoring and to assess information about adherence to reminder emails and

40 correlations between the PROMs and the Disease Activity Score 28 (DAS28).

41

42 Methods. We used an online self-monitoring program in which patients completed disease-specific

43 PROMs in-between their outpatient consultations. Facilitators and barriers regarding self-monitoring

44 were qualitatively assessed through a focus group discussion and telephone interviews. Adherence

45 and correlations were quantitatively assessed.

46

47 Results. Forty-seven patients participated and three themes were identified: knowledge about and

48 insight into disease (activity), patient-professional interaction, and functionality of the program.

49 Patients explained that they gained more knowledge about their disease, felt less dependent on their

50 healthcare professional, and valued the insight into their long-term disease course. Barriers were

51 mostly related to technical factors. Mean adherence to the PROM reminder emails was 68.1%.

52 Rheumatoid Arthritis Impact of Disease (RAID) showed the best congruence with DAS28 scores. Mean

53 participation time was 350 days.

54

55 Conclusion. This pilot study shows the potential of self-monitoring being a part of personalized

56 healthcare. Patients were predominantly positive about the concept of self-monitoring. Self-

57 monitoring has the potential to contribute to a more efficient allocation of outpatient consultations.

58 Further research will however be needed to determine the cost-effectiveness of self-monitoring.

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59 **Article summary**

60

61 Strengths and limitations of this study:

62

63 • This study provides a thorough understanding of the influencing factors regarding self-

64 monitoring, which was explored by both qualitative and quantitative research methods

65 • Patients were positive about the concept of self-monitoring and gave valuable comments for

66 further development of the self-monitoring program

67 • Because of the small study population, it is not clear which percentage of the total IRD

68 population is able and willing to participate in self-monitoring activities

69 • It remains unclear if our self-monitoring program can contribute to reductions in outpatient

70 consultations

3

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71 **Introduction**

72 In chronic care, there is a tendency toward personalized healthcare. Patients have become more

73 empowered and are increasingly involved in the planning and development of healthcare.[1 2] There is a

74 shift from a paternalistic model (in which the doctor is dominant and believes that patients need to be

75 guided through the decision making process) to a shared-decision making model (in which doctor and

76 patient make mutual, collaborative decisions). This shift requires an engaged patient who takes

77 responsibilities regarding day-to-day disease management.[3-6] As a result of this shift, new roles for

78 both patients and healthcare professionals (HCPs) have arisen. An example of what this new role

79 entails for a patient is self-monitoring, in which a patient undertakes self-measurement of vital signs,

80 symptoms, behavior, or psychological well-being through Patient-Reported Outcome Measures

81 (PROMs).[7 8] In some patients with Inflammatory Rheumatic Diseases (IRDs) such as Rheumatoid

82 Arthritis (RA), Psoriatic Arthritis (PsA), or Ankylosing Spondylitis (AS), self-monitoring can gradually

83 replace the traditional monitoring by HCPs.[9]

84 There are however also other reasons why self-management in patients with IRD has gained

85 more interest. Usual care in patients with IRDs is primarily aimed at suppressing disease activity, in

86 order to prevent structural damage.[10 11] The Treat-to-Target Task Force recommends rheumatologists

87 to monthly assess patients with moderate or high disease activity, and patients with controlled and

88 low disease activity every three to six months.[12] In practice, however, these frequencies are not always

89 met for various reasons. This strategy causes time constraints and a growing workload among

90 rheumatologists, making it not manageable for all rheumatologists to comply fully to the frequent

91 assessments.[13] Another reason is connected to the aging population. The number and proportion of

92 patients with IRDs aged 65 and over will increase in the near future.[14] Self-monitoring could prove to

93 be a solution in diminishing the number of consultations.[15] As disease activity can only be objectively

94 assessed during outpatient consultations, it remains unclear what happens with the disease activity

95 in-between consultations. Fluctuations and peeks in disease activity are easily missed or they remain

96 unnoticed, which could have disastrous consequences regarding joint damage.[10] Self-monitoring might

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97 give a better insight into these fluctuations of the disease activity in-between outpatient clinical

98 consultations. Moreover, some patients visit their rheumatologist while their disease activity is under

99 control, thereby contributing to unnecessary outpatient consultations. Summarizing, self-monitoring

100 in IRDs as a first step toward personalized healthcare enables patients as well as HCPs to get insight

101 into the disease activity course over time. Moreover, it may lead to a more consistent reporting in the

102 long term and may contribute to optimizing the number, timing, and efficiency of consultations.[9 15] By

103 completing PROMs, patients who need further medical attention can be identified and receive

104 additional medical attention. Moreover, completion of a PROM will help a patient to prepare for a visit

105 and it could improve the communication between physician and patient.[16]

106 In the present study, an online self-monitoring program was pilot-tested. The aim of this study

107 was twofold. Firstly, this study aimed to obtain experiences (facilitating factors and barriers) regarding

108 online remote monitoring in patients with IRDs. Secondly, information about adherence to PROM

109 reminder emails and correlations between the PROMs and the Disease Activity Score 28 (DAS28) were

110 assessed.

5

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111 **Methods**

112 *Study design*

113 This study was conducted at a teaching hospital in Uden (the Netherlands) at the rheumatology

114 outpatient clinic from 6 July 2015 until 9 May 2017.

115

116 *Study participants*

117 In order to be eligible for this study, patients had to be diagnosed with an IRD according to the

118 ACR/EULAR criteria.[17] Other criteria included having an electronic device (laptop/PC, tablet or

119 Smartphone) with access to the Internet, and being able to sufficiently read and write Dutch. Patient

120 inclusion started in July 2015 and we included the last patient in October 2016.

121

122 *Follow-up duration*

123 Patients were able to withdraw from the program at any time point. We defined early study

124 termination in two manners: when a patient reported to withdraw from the self-monitoring program,

125 this was evaluated as the end date. Some patients did not report dropping out of the study but did

126 stop completing PROM(s). End of study was set by adding the interval time to the date the last PROM

127 was filled in. For example, a patient with a four-week PROM frequency (28 days) completed the last

128 PROM on 1 March 2017. For this patient, end of study date was set on 29 March 2017.

129

130 *Self-monitoring program*

131 iMonitor, the online self-monitoring program tested in this study, was developed by Pfizer.[18] The

132 program was accessible through a laptop, tablet or Smartphone by filling in a user name, password,

133 and pin code. The program complied with the required privacy standards. The system generated an

134 email-alert for filling in a PROM (or PROMs) at a frequency (one-, two-, six- or eight-weekly) which was

135 selected in advance by the patient. Patients were given 24 hours to complete one or more PROMs.

136 Available PROMs for patients with RA were the following: Health Assessment Questionnaire (HAQ),

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137   Rheumatoid Arthritis Impact of Disease (RAID), and/or Rheumatoid Arthritis Disease Activity Index-5

138   (RADAI-5). Patients with Spondylarthropathies (SpA) could fill in the HAQ, the Bath Ankylosing

139   Spondylitis Disease Activity Index (BASDAI) and/or Bath Ankylosing Spondylitis Functional Index

140   (BASFI). Patients could opt to assess one to three PROMs. Completion of all PROMs took about 5

141   minutes. After completion, the PROM scores were subsequently displayed in a graph. Additionally,

142   DAS28 scores could be added to the graph by the HCP. iMonitor was accessible to both patients and

143   HCPs.

144

145   *Procedure*

146   Patients were informed about this pilot study and recruited in several ways. Firstly, we used purposive

147   sampling: rheumatologists themselves asked patients to participate during outpatient consultations.

148   Secondly, during general information meetings at the hospital, patients were informed about the study

149   and were able to sign up. Lastly, leaflets about the study were available in the waiting room and

150   patients were informed about the study through the hospital's website. Patients received a manual

151   containing information regarding access to and use of the program. However, a substantial number

152   needed additional training, which was provided by instruction classes. After patients had been

153   instructed how to use the program, they could indicate which PROM(s) they preferred to fill in by

154   showing them the paper versions. Moreover, they were asked to indicate their desired frequency

155   option. Patients who agreed to take part in the study were asked to sign a consent form.

156

157   *Data collection and analysis*

158   Quantitative

159   ▪   Adherence and congruence

160   The study aims for the quantitative part of this study were twofold. Firstly, we determined adherence

161   to the alert-emails. This was done by assessing whether a patient had completed (yes or no) the

162   PROM(s) in the predetermined time interval. Adherence was calculated as the number of completed

7

163 assessments by the patient divided by the number of assessments that should have been assessed

164 according to the chosen interval of the patient times 100%. Patients who only completed a PROM(s)

165 once were excluded in this adherence analysis. Secondly, we determined the congruence between

166 DAS28 scores and PROM values. Two researchers (LR and PvR) independently assessed congruence by

167 comparing the DAS28 course with the corresponding PROM-value(s) using two categories (poor and

168 good) and discussed discrepancies. Data from patients with at least three PROM values (falling within

169 a fourteen-day-window with DAS28 assessment) were assessed.

170

171 Qualitative

172 Patient experiences with the self-monitoring program were obtained via a focus group and semi-

173 structured interviews. The purpose of the focus group and interviews was to gain insight into the

174 barriers and facilitators encountered by patients. The framework from Flottorp et al.[19] served as an

175 inspiration for a semi-structured topic guide. This framework identifies factors that might hinder or

176 facilitate the implementation of innovations. For this study we used the framework to identify

177 facilitating factors and barriers regarding online remote monitoring. Prior to the start of the focus

178 group discussion we conducted a telephone interview with one patient to check the appropriateness

179 of the topic guide and to check whether the questions were clear. During the focus group discussion,

180 an experienced moderator (PvR) guided the discussion. Patients unable to attend the focus group were

181 interviewed by telephone, using the same topic guide. All participating patients had at least six months

182 experience with the self-monitoring program. The interviews and focus group discussion were

183 recorded and transcribed ad verbum, while two researchers independently coded the transcripts. A

184 constant comparative method was used for the analysis of the emerging themes. We conducted coding

185 and analysis by using a qualitative software program (Atlas.ti).

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186 *Patient and public involvement*

187 Firstly, patient involvement was needed during the establishment of the topic guide, which was pre-

188 tested among one patient in order to check if the questions were comprehensible and clear. Secondly,

189 patients were encouraged to give suggestions and comments regarding the use of the program during

190 the entire study period. This feedback was used as input for the implementation of a revised version

191 of the program at a later stage. Lastly, the study participants exchanged their experiences with the

192 self-monitoring program with other patients (users and non-users) during research meetings at the

193 hospital.

194

195 **Results**

196 *Study population*

197 In this pilot study, slightly more women than men participated (n=27; 57.4%). Mean($\pm$) age was

198 57.3(10.7) years. Most patients (n=38) were diagnosed with RA (80.9%), while nine patients were

199 diagnosed with a SpA (eight patients with PsA, and one patient with AS). Other baseline characteristics

200 are given in Table 1. During the study period we included 47 patients. Patient inclusion started in July

201 2015 and we included the last patient in October 2016. Two patients eventually signed the informed

202 consent form but did not complete any PROMs and were withdrawn from the study. An overview of

203 the follow-up duration is presented in Figure 1. In total, twenty-three patients participated from the

204 start (different start dates were possible) until the end of the study (48.9%). The follow-up duration of

205 the 45 patients who completed PROMs varied between 14 and 597 days, with a mean of 350 days.

206

207 < Figure 1. Overview of the follow-up duration of the 47 iMonitor participants >

9

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208   Table 1. Baseline characteristics of the 47 patients using the self-monitoring program

209

Characteristics	Rheumatoid arthritis, n = 38	SpA group, n = 9
Patient and disease characteristics		
Age, years, mean (SD)	57.74 (11.17)	55.67 (8.69)
Female, n (%)	20 (52.6%)	7 (77.8%)
Disease duration, years, mean (SD)	8.08 (4.74)	9.89 (7.25)
DAS28-score, mean (SD)	3.19 (1.25)	n.a.
Educational level		
Low, n (%)	12 (34.3)	3 (37.5)
Middle, n (%)	11 (31.4)	3 (37.5)
High, n (%)	12 (34.3)	2 (25.0)
Baseline PROM-values		
HAQ [0.00-3.00] (n=27), mean, SD, range	0.78 (0.61) [0.00;2.38]	0.98 (0.60) [0.13;1.88]
RADAI-5 [0.00 – 10.00] (n=24), mean, SD, range	3.49 (2.32) [0.00;7.40]	n.a.
RAID [0.00 – 10.00) (n=35) mean, SD, range	3.47 (2.28) [0.00;7.61]	n.a

10

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BASFI [0.00 – 10.00] (n=1), mean, SD	n.a.	5.05
BASDAI [0.00 – 10.00] (n=1), mean, SD	n.a.	4.60

210   *SpA: Spondylarthropathy; PROM: Patient-Reported Outcome Measure; HAQ: Health Assessment Questionnaire (3 = severe disability); RADAI-5: Rheumatoid Arthritis Disease*
211   *Activity Index-5 (10 = severe disease activity); RAID: Rheumatoid Arthritis Impact of Disease (10 = severe impact of disease activity); BASFI: Bath Ankylosing Spondylitis*
212   *Functional Index (10 = severe functional limitation); BASDAI: Bath Ankylosing Spondylitis Disease Activity Index (10 = severe disease activity)*

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213 *Quantitative*

214 ▪ Adherence and congruence

215 Twenty-seven patients (57.4%) were able to use the self-monitoring program without additional

216 training, whereas twenty patients (42.6%) attended the instruction classes. With regard to the PROM

217 preferences, RAID was chosen most often, namely 34 times. HAQ and RADAI-5 were chosen 27 and 23

218 times, respectively. Seventeen patients chose to complete one PROM, 21 patients chose to complete

219 two PROMs, and nine patients chose to complete three PROMs. Mean adherence to reminder emails

220 was 68.1%, see table 2. With regard to the congruence between the DAS28 score and PROM values,

221 RAID scored best (from 25 assessments, 17 times a score of 'good', 68.0%). RADAI-5, on the other

222 hand, scored 'good' in ten out of seventeen assessments (58.8%), see table 3. Figure 2 shows two

223 examples of assessments regarding the congruence between the PROMs and DAS28 scores.

224

225 Table 2. Data regarding PROM frequency, PROM scores, and adherences rates, n = 47

Item	n (%)
PROM frequency	
1 week	4 (8.5)
2 weeks	10 (21.3)
4 weeks	31 (66.0)
≥ 6 weeks	2 (4.3)
Number of PROMs to complete, chosen by patient	
One	17 (36.17)
Two	21(44.68)
Three	9 (19.15)
Mean adherence (%) to PROM reminders	68.1%

226 *PROM: Patient-Reported Outcome Measure; Adherence: calculated as person time frequency: dividing the*

227 *number of completed PROMs by the number of PROM-assessments that should have been completed according*

228 *to the chosen PROM frequency, times 100*

229

230 < Figure 2. Example of a positive (above) and negative (below) rating regarding the PROM-DAS28

231 congruence >

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232   Table 3. Congruence (poor or good) between DAS28 scores and RAID and RADAI-5, assessed in n = 33

233   patients

PROM	Poor	Good	Total
RAID	8 (32.0%)	17 (68.0%)	25
RADAI-5	7 (41.2%)	10 (58.8%)	17

234   *PROM: Patient-Reported Outcome Measure; RAID: Rheumatoid Arthritis Impact of Disease; RADAI-5:*

235   *Rheumatoid Arthritis Disease Activity Index-5*

236

237   *Qualitative*

238   We conducted the focus group discussion and telephone interviews between December 2016 and June

239   2017. The interviews lasted between 24 and 42 minutes, while the focus group discussion lasted one

240   hour and 22 minutes. Six patients attended the focus group discussion, and four patients participated

241   in a telephone interview (five female and five male patients).

242

243   *Influencing factors regarding the self-monitoring program*

244   Three main themes emerged from the focus group discussion and interviews: knowledge about and

245   insight into disease (activity), patient-professional interaction, and functionality of the program. Five

246   subcategories emerged: Disease (self)management, discussing results with healthcare professionals,

247   technical factors, user interface and PROMs, and patients' suggestions for improvement. Table 4

248   provides an overview of the themes and subcategories regarding the qualitative analysis.

249

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251 Table 4. Themes and subcategories with regard to the qualitative analysis of barriers and facilitators

252 using iMonitor

Theme	Subcategory
Knowledge about and insight into disease (activity)	n.a.
Patient-professional interactions	- Disease (self)management - Discussing results with healthcare professionals
Functionality of the program	- Technical factors - User interface and PROMs - Patients' suggestions for improvement

253 *Three main themes and five subcategories emerged from the qualitative analysis. The framework from Flottorp*

254 *et al.[19] served as a guide for the establishment of the topic guide*

255

256 *Theme I: Knowledge about and insight into disease (activity)*

257 The most cited reason for using the self-monitoring program was that patients gained insight into their

258 (long-term) disease activity course. Most patients indicated that using the program led to more

259 knowledge and awareness about their disease. Some patients reported that they recognized peaks in

260 disease activity earlier and could subsequently prepare for an exacerbation. Patients also mentioned

261 that they became more prudent when noticing a flare. When asked more specifically about patients'

262 experiences with the congruence between their PROM values and DAS28 scores, most patients

263 thought their PROM values were in line with their DAS28.

264 *"By consciously using the program, it was easier to find things about rheumatism and to gain more*

265 *insight into the question 'What is rheumatism?'"*

14

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266   *Theme II: Patient-professional interactions*

267   ▪   Disease (self)management

268   By using the self-monitoring program, most patients felt less dependent on their HCP. Patients

269   appreciated the fact that they were able to influence their own disease management. Overall, patients

270   thought that the self-monitoring program could contribute to a reduction in the number of outpatient

271   consultations.

272

273   *"I can monitor my disease course, keep record of my disease activity in-between consultations, without*

274   *being dependent on the professional"*

275

276   ▪   Discussing results with healthcare professionals

277   Patients emphasized the importance of discussing the results of online monitoring (e.g. PROM values)

278   with their HCP (rheumatologist or nurse). Most of all, they wanted to know if they were 'doing it right'.

279   Some patients expressed the value of discussing their results with their HCP. One patient provided the

280   following scenario: *'I used to look at the back of a computer screen during an outpatient visit. Now, I'm*

281   *looking at the computer screen together with my HCP, sharing and discussing the PROM values and our*

282   *ideas about my treatment'*. Patients who did not discuss their values felt the need to do so in the

283   future.

284

285   *Theme III: Functionality of the program*

286   ▪   Technical factors

287   Barriers regarding the use of the self-monitoring program were mostly related to technical aspects.

288   Some patients had problems with the login system, which hindered them from accessing the website.

289   Regarding the PROM reminder emails: the system generated an email alert at fixed time points (e.g.

290   four-weekly). Some patients noticed that the system generated an alert at unfortunate time points or

291   even no alert at all.

15

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292   ▪   User interface and PROMs

293 Twenty-seven patients joined the instruction classes, which were perceived to be very helpful. Overall,

294 patients were satisfied with the user interface of the program. They reviewed the layout as clear and

295 comprehensible. Some patients experienced difficulties with the content and layout of the PROMs. For

296 example, some patients thought the questions were not specific enough. Furthermore, the program

297 did not use a progress bar and there was no 'Accomplish' sign after completing a PROM. As a result –

298 in case of completing more than one PROM – some patients did not know how many PROMs they had

299 actually completed.

300

301   ▪   Patients' suggestions for improvement

302 Most commonly mentioned suggestions concerned adjustments to clarify PROM values, for example

303 a textbox to type a comment in case of an exacerbation. Additionally, patients provided suggestions

304 concerning the possibility of also having access to their lab values in the self-monitoring program, as

305 well as the possibility of having a more detailed look at a certain time period.

16

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306 **Discussion**

307 This study collected experiences from patients with IRDs regarding online self-monitoring. Moreover,

308 we assessed adherence to the predefined PROM frequency to measure disease activity and the

309 congruence between the PROMs and the DAS28. The qualitative analysis revealed three themes:

310 knowledge about and insight into disease (activity), patient-professional interaction, and functionality

311 of the program. Overall, patients were mainly positive about the program and were willing to continue.

312 Most of them participated for an extended period: mean follow-up duration was almost one year, and

313 mean adherence to the predefined PROM frequency was 68.1%. Patients reported that they gained

314 more knowledge about their disease and felt less dependent on their HCP.

315

316 By self-monitoring disease activity, patients obtained a graphic overview of their PROM values over

317 time, which gave them insight into their disease course. Patients reported that they appreciated both

318 this long-term insight into their disease pattern, and the ability to anticipate on an exacerbation. They

319 also indicated that they gained more knowledge about their disease, they felt better prepared for a

320 consultation, and felt less dependent on their HCP in handling their disease. Literature about self-

321 monitoring in diabetes already showed that knowledge about the disease and self-monitoring are

322 related[8]. Although some knowledge is a prerequisite for self-monitoring, the process of self-monitoring

323 contributes to the further expansion of disease-related knowledge. Adequate disease-related

324 knowledge is important, since it may influence patients' decisions regarding treatment, compliance,

325 and self-management performance,[20] as well as the ability to recognize signs, symptoms, and

326 patterns.[8] All of these aspects are essential in shared-decision making,[21] while also being beneficial to

327 the efficiency of consultations. From the perspective of the HCP, it is important to give feedback to the

328 patients about the results of self-monitoring, a fact that was emphasized by our study participants

329 during the interviews. Those who had not received feedback about their PROM-values and/or disease

330 activity course were less motivated to continue with the program. The importance of feedback was

331 emphasized in a study in which patients with early rheumatoid arthritis received visual feedback by

17

332   their HCP about their disease progression. Compared to patients who received standard care, patients

333   who received feedback showed significant differences regarding disease activity parameters.[22]

334   Obtaining insight into the long-term disease activity course, and being able to anticipate on an

335   exacerbation, might benefit the effectiveness of the delivered care as well. Patients will be able to

336   respond to a deterioration in a timely manner and will have a greater chance to receive the care they

337   need at the right time, resulting in a decrease of the cumulative disease activity. On the other hand,

338   fewer consultations are possible if the disease activity is stable, which will eventually lead to less

339   frequent outpatient visits. Studies on self-monitoring in other chronic diseases have already proven its

340   effectiveness, such as better control of blood glucose levels in diabetes,[23 24] reduction in mortality rates

341   in heart failure,[25 26] reductions in blood pressure in hypertension,[27 28] and reductions in

342   thromboembolic events in patients using anticoagulation therapy.[29] The effectiveness of self-

343   monitoring resulted in a reduction in hospital readmissions in patients with hypertension, COPD and

344   heart failure.[30] Patients in our study believed that self-monitoring could lead to a reduction in

345   consultations, although they stressed the need and possibility for contacting the outpatient clinic when

346   necessary. To our knowledge, there are no studies in IRDs on the efficiency of online remote self-

347   monitoring by completing PROMs on reduction in consultations. Further research will therefore be

348   needed.

349

350   Barriers regarding online self-monitoring were mostly related to the functionality of the online

351   monitoring system. Some patients experienced log-on problems, while others would like to have

352   access in the system to more extensive information about their health status in general (e.g. blood test

353   results). Literature in the field of technology and innovations indicates that factors such as

354   compatibility, complexity, and relative advantage influence the adoption of new innovations.[31]

355   Therefore, a self-monitoring program should be comprehensible and user-friendly and preferably

356   integrated into an existing hospital system. In addition, we recommend screening patients on

357   motivation and computer skills and providing guided practice. Despite experienced barriers, almost

358 half of the participants reached the end of the study, and the follow-up duration was almost one year.

359 Since there was no real 'need' or urgency for self-monitoring in our study, as opposed to blood glucose

360 monitoring in diabetes, for example, reaching complete (100%) adherence was not a realistic option.

361 Even so, adherence to the PROM frequency was reasonably high. Sending reminders to fill in PROMs

362 was possibly related to these reasonably high rates, and was considered by the patients to be very

363 useful.

364

365 By using qualitative methods we were able to examine the experiences and barriers that influence

366 participation in self-monitoring programs. This resulted in a thorough understanding of the concept of

367 self-monitoring, and guidance for further development. The main limitation of this study was the

368 selective, highly motivated study population. Of over 1800 patients with an IRD at the outpatient clinic,

369 47 patients participated. Because of the small study sample, it remains unclear which percentage of

370 the total population will be eligible for self-monitoring. However, the main purpose was to gather

371 experiences about self-monitoring, which were provided by the extensive comments of the patients.

372

373 In the present study, patients were willing and able to self-monitor their disease. By monitoring their

374 disease activity at home, they were involved in their own disease management and had individual

375 control and responsibilities. During outpatient visits, patients might be better prepared to interact with

376 their HCP, which will improve shared-decision making, contributing to the concept of personalized

377 care. Self-monitoring – as a prerequisite of self-management – might benefit the cost-effectiveness of

378 outpatient consultations. Efficiency gains are reflected in a reduction in the number of consultations

379 without any increase in costs. At the same time, patient outcomes and patients' satisfaction should

380 either remain stable or increase. This study is a first step toward personalized healthcare and involving

381 the patient in decision making about their disease treatment. Findings from our study were used to

382 implement a self-monitoring program at our outpatient clinic using the Integrated Electronic Patient

383 Record from the hospital.

19

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384   The present study showed the potential of self-monitoring as a first step toward disease self-

385   management. Patients reported that they gained more knowledge, felt less dependent on their HCP,

386   and most of them were able to monitor their disease. Therefore, we believe that self-monitoring can

387   benefit the quality and efficiency of healthcare. Further research will be needed to confirm the cost-

388   effectiveness of self-monitoring.

389

390   **Acknowledgment**

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393

394   **Contributors**

395   The final manuscript has been seen and approved by all authors. PvR was involved in the study

396   acquisition. All authors contributed in the study design process. PvR and LR collected the qualitative

397   data. LR collected the quantitative data. LR was involved as one of the coders during the coding

398   process. All authors were involved in the data analysis, as well as in the writing process.

399

400   **Conflicts of interest**

401   None declared.

402

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405

406   **Ethics**

407   The Medical Ethical Committee of the Radboud University Medical Center Nijmegen approved the

408   study (2016-2435) and concluded that no specific obligations were applicable to this research.

409

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410 **Data**

411 Additional data is available from the corresponding author on reasonable request.

21

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Figure 1. Follow-up duration in days of the 47 iMonitor participants
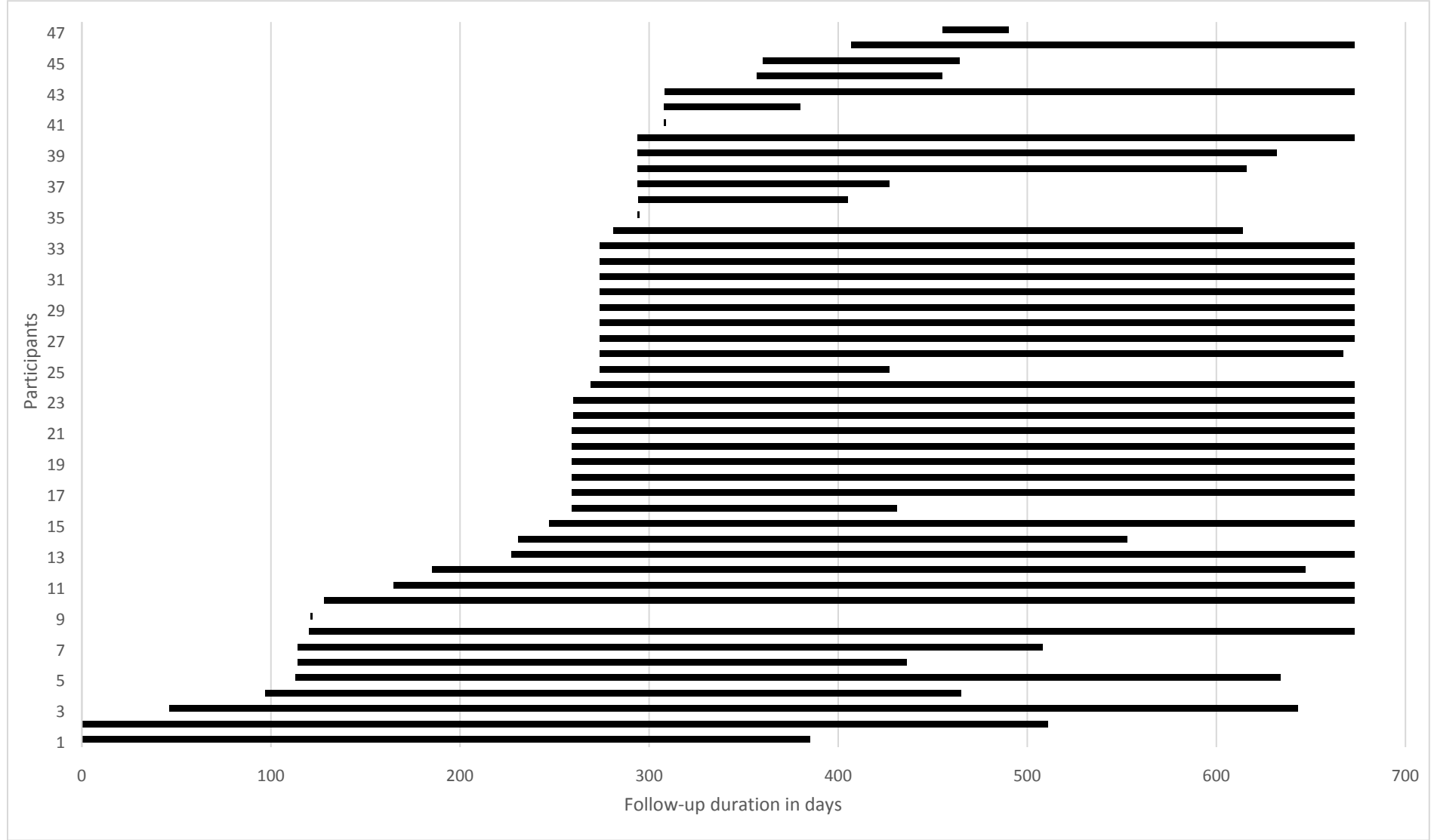
Y-axis: 47 patients who participated in the self-monitoring program, each line represents a patient; X-axis: days since start of study (different start days possible for patients)

Figure 2. Example of a positive (above) and negative (below) rating regarding the PROM-DAS28 congruence
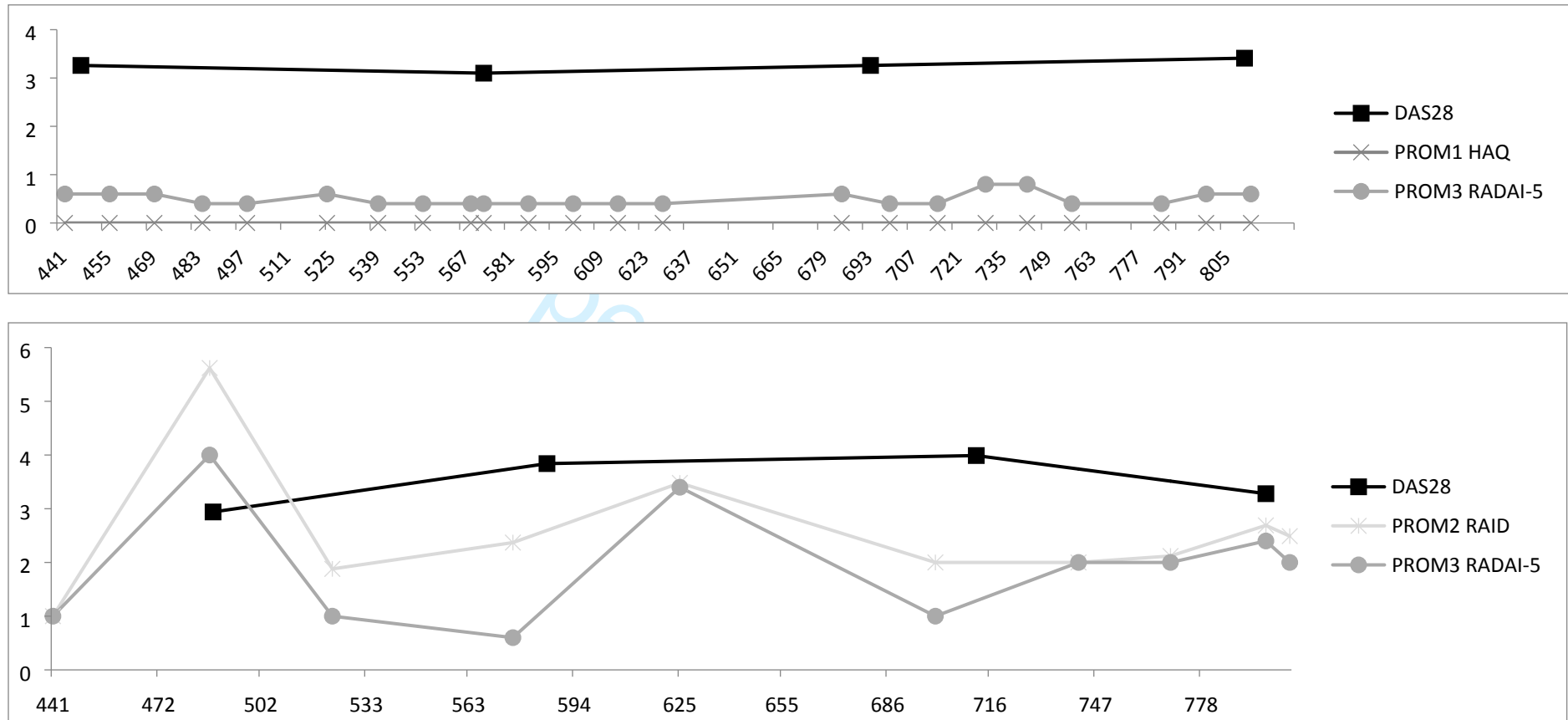
DAS28: Disease Activity Score 28; PROM: Patient-Reported Outcome Measure; HAQ: Health Assessment Questionnaire; RADAI-5: Rheumatoid Arthritis Disease Activity Index-5; RAID: Rheumatoid Arthritis Impact of Disease.

Above: good congruence between PROM-values and DAS28-scores. Below: poor congruence between PROM-values and DAS28-scores

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Patients' experiences regarding self-monitoring of the disease course: an observational study in patients with Inflammatory Rheumatic Diseases

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1 **Full title**

2 Patients' experiences regarding self-monitoring of the disease course: an observational study in

3 patients with Inflammatory Rheumatic Diseases

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36

37   **Abstract**

38   Objectives. Self-monitoring the disease course is a relatively new concept in the management of

39   patients with Inflammatory Rheumatic Diseases (IRDs). The aims of this pilot study were to obtain

40   patients' experiences with online self-monitoring, to assess information about the agreement between

41   the disease course assessed with Patient Reported Outcome Measures (PROMs) and an objectively

42   measured Disease Activity Score by the rheumatologist (DAS28), and to assess adherence to

43   predetermined PROM frequency intervals.

44

45   Design. Observational study using qualitative and quantitative methods.

46   Setting. The rheumatology outpatient clinic of a teaching hospital in the Netherlands (secondary care).

47   Participants: 47 Patients with an IRD who regularly attended the outpatient clinic.

48

49   Methods. Patients completed PROMs by using an online self-monitoring program. Their experiences

50   regarding self-monitoring were qualitatively assessed through a focus group discussion and telephone

51   interviews using a thematic analysis approach. Adherence to the predefined PROM frequency

52   (completed PROM assessments within the predetermined frequency) and the agreement between the

53   DAS28 course and PROM values (Rheumatoid Arthritis Disease Activity Index-5 (RADAI-5) and the

54   Rheumatoid Arthritis Impact of Disease (RAID)) were quantitatively assessed using descriptives.

55

56   Results. Forty-seven patients participated, most of them diagnosed with RA (n = 38, 80.9%). Three

57   themes were identified: knowledge about and insight into disease (activity), patient-professional

58   interaction, and functionality of the program. Mean adherence to the predetermined PROM frequency

59   was 68.1%. The RAID showed the best agreement with the DAS28 course. Mean participation time was

60   350 days.

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61

62 Conclusion. Patients were predominantly positive about online self-monitoring. They indicated that

63 they gained more knowledge about their disease, felt less dependent on the healthcare professional,

64 and valued the insight into their long-term disease course. Barriers were mostly related to technical

65 factors. Patients were able to and willing to self-monitor their disease, which could contribute to a

66 more efficient allocation of outpatient consultations in the future.

67

68

3

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69 **Article summary**

70

71 Strengths and limitations of this study:

72

73 • A strength of this study is the use of both qualitative and quantitative research methods,

74 providing a rich understanding of factors associated with self-monitoring

75 • Patients were closely involved during the development stage, execution, and evaluation

76 stage of this study

77 • Using validated Patient Reported Outcome Measures (PROMs) allowed us to both examine

78 what really matters to patients and to compare these PROM scores with objective scores

79 • Due to the selective and small study population it is not clear which percentage of the total

80 population with IRD is willing to and able to self-monitor the disease course

81

4

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82 **Introduction**

83 In chronic care, there is a tendency toward personalized healthcare. Patients have become more

84 empowered and are increasingly involved in the planning and development of healthcare.[1-4] There is a

85 shift from a paternalistic model (in which the doctor is dominant and believes that patients need to be

86 guided through the decision making process) to a shared-decision making model (in which doctor and

87 patient make mutual, collaborative decisions). This shift requires an engaged patient who takes

88 responsibilities regarding day-to-day disease management.[5-8] As a result of this shift, new roles for

89 both patients and healthcare professionals (HCPs) have arisen. An example of what this new role

90 entails for a patient is self-monitoring, in which a patient undertakes self-measurement of vital signs,

91 symptoms, behavior, or psychological well-being through Patient-Reported Outcome Measures

92 (PROMs).[9 10] In some patients with Inflammatory Rheumatic Diseases (IRDs) such as Rheumatoid

93 Arthritis (RA), Psoriatic Arthritis (PsA), or Ankylosing Spondylitis (AS), self-monitoring can gradually

94 replace the traditional monitoring by HCPs.[11] Examples of disease-specific PROMs in IRDs that can be

95 used in self-monitoring are the Rheumatoid Arthritis Impact of Disease[12] (RAID), which measures

96 disease impact, and the Rheumatoid Arthritis Disease Activity Index-5[13] (RADAI-5), which measures

97 disease activity. An example of a general or non-specific PROM is the Health Assessment Questionnaire

98 (HAQ), measuring functional status.

99   There are however also other reasons why self-monitoring in patients with IRD has gained

100 more interest. Usual care in patients with IRDs is primarily aimed at suppressing disease activity, in

101 order to prevent structural damage.[14 15] The disease activity can be measured using a composite index,

102 the Disease Activity Score using 28 joint counts[16], which measures tender and swollen joint counts,

103 acute phase response, and a patient's general health assessment. The Treat-to-Target Task Force

104 recommends rheumatologists to monthly assess patients with moderate or high disease activity, and

105 patients with controlled and low disease activity every three to six months.[17] In practice, however,

106 these frequencies are not always met for various reasons. This strategy causes time constraints and a

107 growing workload among rheumatologists, making it not manageable for all rheumatologists to comply

5

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108   fully to the frequent assessments.[18] Another reason is connected to the aging population. The number

109   and proportion of patients with IRDs aged 65 and over will increase in the near future.[19] Self-

110   monitoring of the disease course using disease-specific PROMs such as RAID or RADAI-5 could prove

111   to be a solution in diminishing the number of consultations.[20] As disease activity can only be objectively

112   assessed during outpatient consultations, it remains unclear what happens to the disease activity in-

113   between consultations. Fluctuations and peeks in disease activity are easily missed or they remain

114   unnoticed, which could have disastrous consequences regarding joint damage.[14] Self-monitoring might

115   also give a better insight into these fluctuations of disease activity in-between outpatient clinical

116   consultations. Moreover, some patients visit their rheumatologist while their disease activity is under

117   control, thereby contributing to unnecessary outpatient consultations. Summarizing, self-monitoring

118   of disease activity in IRDs as a first step toward personalized healthcare enables patients as well as

119   HCPs to get insight into the disease activity course over time. Moreover, it may lead to a more

120   consistent reporting in the long term and may contribute to optimizing the number, timing, and

121   efficiency of consultations.[11 20] By completing PROMs, patients who need further medical attention can

122   be identified and receive additional medical attention. Moreover, completion of a PROM will help a

123   patient to prepare for a visit and it could improve the communication between physician and patient.[21]

124   [22]

125   In the present study an online self-monitoring program was pilot-tested in order to test the

126   feasibility of self-monitoring before implementation of a self-monitoring program in daily clinical

127   practice. The aims of this study were to obtain patients' experiences regarding online self-monitoring,

128   to assess the agreement between the disease course assessed with disease-specific PROMs (RAID and

129   RADAI-5) and an objectively measured disease activity score (DAS28) by the rheumatologist, and to

130   assess the adherence to predetermined PROM frequency intervals.

131

6

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132 **Methods**

133 *Study design*

134 This observational study using quantitative and qualitative research methods, was conducted at a

135 teaching hospital in Uden (the Netherlands) at the rheumatology outpatient clinic from 6 July 2015

136 until 9 May 2017.

137

138 *Inclusion criteria*

139 In order to be eligible for this study, patients had to be diagnosed with an IRD according to the

140 ACR/EULAR criteria.[23] Patients should also have an electronic device (laptop/PC, tablet or Smartphone)

141 available with access to the Internet, and being able to sufficiently read and write Dutch. Patient

142 inclusion started in July 2015 and we included the last patient in October 2016.

143

144 *Follow-up duration*

145 Patients were able to withdraw from the program at any time point. We defined early study

146 termination in two manners: when a patient reported to withdraw from the self-monitoring program,

147 this was evaluated as the end date. Some patients did not report dropping out of the study but did

148 stop completing PROM(s). End of study in these cases was set by adding the interval time to the date

149 the last PROM was filled in. For example, a patient with a four-week PROM frequency (28 days)

150 completed the last PROM on 1 March 2017. For this patient, end of study date was set on 29 March

151 2017.

152

153 *Self-monitoring program*

154 iMonitor, the online self-monitoring program tested in this study, was developed by Pfizer.[24] The

155 program was accessible through a laptop, tablet or Smartphone by filling in a user name, password,

156 and pin code. The program complied with the required privacy standards. Because the program was

157 intended to stimulate patient involvement, personalized healthcare and patient self-management,

7

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158   patients selected their preferred PROM(s) and PROM frequency (one-, two-, four-, six- or eight-weekly)

159   in advance and the system generated an email-alert for filling in a PROM (or PROMs) accordingly.

160   Patients were able to complete one or more PROMs within a timeframe of 24 hours. They could send

161   a message to the HCPs in case of questions or notifications by using the message option. In case of

162   urgent matters, they could contact the outpatient clinic by telephone.

163

164   *Patient-Reported Outcome Measures (PROMs)*

165   Available disease-specific PROMs for patients with RA were the RAID and the RADAI-5, measuring

166   disease impact (0-10; 10 = severe impact of disease activity) and disease activity (0-10; 10 = severe

167   disease activity). Patients with AS could fill in the disease-specific Bath Ankylosing Spondylitis Disease

168   Activity Index (BASDAI), measuring disease activity (0-10; 10 = severe disease activity), and/or the Bath

169   Ankylosing Spondylitis Functional Index (BASFI), measuring physical function (0-10; 10 = severe

170   functional limitation). The HAQ, general PROM that measures physical function, was available for all

171   patients (0-3; 3 = severe disability). Patients could opt to assess one to three PROMs. Completion of all

172   PROMs took about 5 minutes. After completion, the PROM scores were subsequently displayed in a

173   graph. Additionally, DAS28 scores (0-10; remission: DAS28 <2.6, low disease activity: ≥ 2.6 DAS28 < 3.2,

174   moderate disease activity: ≥ 3.2 DAS28 ≤5.1, high disease activity: DAS28 > 5.1) could be added to the

175   graph by the HCP. These DAS28 scores were obtained by the HCPs during outpatient consultations and

176   were kept in the electronic medical files from the hospital.

177

178   *Procedure*

179   Patients were informed about this pilot study and recruited in several ways. Firstly, we used purposive

180   sampling: rheumatologists themselves asked possible suitable patients to participate during

181   outpatient consultations during the entire study period. Secondly, during general information

182   meetings at the hospital, patients were informed about the study and were able to sign up. Lastly,

183   leaflets about the study were available in the waiting room and patients were informed about the

8

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184 study through the hospital's website. Patients received a manual containing information regarding

185 access to and use of the program. However, a substantial number needed additional training, which

186 was provided by instruction classes. After patients had been instructed how to use the program, they

187 could indicate which PROM(s) they preferred to fill in by showing them the paper versions. Moreover,

188 they were asked to indicate their desired frequency option. Patients who agreed to take part in the

189 study were asked to sign a consent form. During the regular outpatient consultations, rheumatologists

190 were expected to provide feedback to the patient about the patient's disease course and PROM

191 results.

192

193 *Data collection and analysis*

194 Quantitative methods

195 ▪ Adherence and agreement

196 Firstly, we determined adherence to the predetermined PROM frequency by assessing whether a

197 patient had completed (yes or no) the PROM(s) in the predetermined time interval. Adherence was

198 calculated as the number of completed assessments by the patient divided by the number of PROM

199 assessments that should have been completed according to the chosen interval of the patient times

200 100%. For example, a patient with a weekly PROM frequency participated for one year. This patient

201 should have received 52 email-alerts, so 52 PROM assessments should have been completed. This

202 patient completed 40 PROM assessments, so adherence is (40/52*100 =) 76.9%. Secondly, we

203 determined the agreement between the DAS28 course and PROM values. Two researchers (LR and

204 PvR) independently assessed agreement by comparing the DAS28 course with the corresponding

205 PROM-value(s) from the RAID and/or RADAI-5 using two categories (poor and good) and discussed

206 discrepancies. The RAID and the RADAI-5 were used, because these two disease-specific PROMs

207 measure disease impact and activity, whereas the HAQ is non-disease specific. 'Good' was used in

208 cases where the DAS28 course and the PROM scores showed the same direction (i.e. the DAS28 course

209 increased and PROM scores as well). 'Poor' was used in cases where the DAS28 course and PROM

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210   scores showed opposite directions (the DAS28 course increased and PROM scores decreased (or the

211   other way around). Data from patients with at least three PROM values (falling within a fourteen-day-

212   window with DAS28 assessment) were assessed.

213

214   Qualitative methods

215   Patients' experiences with the self-monitoring program were obtained via a focus group and semi-

216   structured interviews. The purpose of the focus group and interviews was to gain insight into relevant

217   factors that might hinder or facilitate patients using the self-monitoring program. The checklist from

218   Flottorp et al.[25] served as an inspiration for a semi-structured topic guide (see appendix). Relevant

219   domains for our topic guide were: program factors; patient factors; professional-patient interaction

220   factors; and resources. Prior to the start of the focus group discussion we conducted a telephone

221   interview with one patient to check the appropriateness of the topic guide and to check whether the

222   questions were clear. During the focus group discussion, an experienced moderator (PvR) guided the

223   discussion. Patients unable to attend the focus group were interviewed by telephone, using the same

224   topic guide. All participating patients had at least six months experience with the self-monitoring

225   program.

226

227   *Qualitative analysis*

228   The interviews and focus group discussion were recorded. The recordings were and transcribed ad

229   verbum by an independent agency. One of the researchers (LR) and a research assistant independently

230   coded the transcripts to increase intercoder reliability. They used the method 'thematic analysis' in

231   which the codes were derived from the data with the purpose to describe relevant factors regarding

232   self-monitoring and to identify categories and themes. A constant comparative method was used for

233   the analysis of the emerging themes. Any discrepancies in the analysis were discussed until consensus

234   was reached[26]. Afterwards, two researchers (LR and AH) agreed on a provisional categorization and

235   overarching themes. These categories and overarching themes were also discussed with a third and

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236   fourth researcher (SR and PvR). The COnsolidated criteria for REporting Qualitative research (COREQ)

237   checklist[27] was mainly used as guidance for the reporting of our qualitative research. We conducted

238   coding and analysis by using a qualitative software program (Atlas.ti).

239

240   *Patient and public involvement*

241   Firstly, patient involvement was needed during the establishment of the topic guide, which was pre-

242   tested among one patient in order to check if the questions were comprehensible and clear. Secondly,

243   patients were encouraged to give suggestions and comments regarding the use of the program during

244   the entire study period. This feedback was used as input for the implementation of a revised version

245   of the program at a later stage. Lastly, the study participants exchanged their experiences with the

246   self-monitoring program with other patients (users and non-users) during research meetings at the

247   hospital.

248

249   **Results**

250   *Study population*

251   In this pilot study, slightly more women than men participated (n=27; 57.4%). Mean($\pm$) age was

252   57.3(10.7) years. Most patients (n=38) were diagnosed with RA (80.9%), while nine patients were

253   diagnosed with a SpA (eight patients with PsA, and one patient with AS). Other baseline characteristics

254   are given in Table 1. Of over 1800 patients with an IRD, we included 47 patients during the study period.

255   Two patients eventually signed the informed consent form but did not complete any PROMs and were

256   withdrawn from the study. An overview of the follow-up duration is presented in Figure 1. In total,

257   twenty-three patients participated from the start (different start dates were possible) until the end of

258   the study (48.9%). The follow-up duration of the 45 patients who completed PROMs varied between

259   14 and 597 days, with a mean of 350 days.

260

261   < Figure 1. Overview of the follow-up duration of the 47 iMonitor participants >

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262   Table 1. Baseline characteristics of the 47 patients using the self-monitoring program

263

Characteristics	Rheumatoid arthritis, n = 38	SpA group, n = 9
Patient and disease characteristics		
Age, years, mean (SD)	57.74 (11.17)	55.67 (8.69)
Female, n (%)	20 (52.6%)	7 (77.8%)
Disease duration, years, mean (SD)	8.08 (4.74)	9.89 (7.25)
DAS28-score, mean (SD)	3.19 (1.25)	n.a.
Educational level		
Low, n (%)	12 (34.3)	3 (37.5)
Middle, n (%)	11 (31.4)	3 (37.5)
High, n (%)	12 (34.3)	2 (25.0)
Baseline PROM-values		
HAQ [0.00-3.00] (n=27), mean, SD, range	0.78 (0.61) [0.00;2.38]	0.98 (0.60) [0.13;1.88]
RADAI-5 [0.00 – 10.00] (n=24), mean, SD, range	3.49 (2.32) [0.00;7.40]	n.a.
RAID [0.00 – 10.00) (n=35) mean, SD, range	3.47 (2.28) [0.00;7.61]	n.a

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BASFI [0.00 – 10.00] (n=1), mean, SD	n.a.	5.05
BASDAI [0.00 – 10.00] (n=1), mean, SD	n.a.	4.60
Medication use		
csDMARD, n (%)	36 (94.7%)	8 (88.9%)
bDMARD, n (%)	12 (32.0%)	3 (33.3%)

264   *SpA: Spondylarthropathy; PROM: Patient-Reported Outcome Measure; HAQ: Health Assessment Questionnaire (3 = severe disability); RADAI-5: Rheumatoid Arthritis Disease*
265   *Activity Index-5 (10 = severe disease activity); RAID: Rheumatoid Arthritis Impact of Disease (10 = severe impact of disease activity); BASFI: Bath Ankylosing Spondylitis*
266   *Functional Index (10 = severe functional limitation); BASDAI: Bath Ankylosing Spondylitis Disease Activity Index (10 = severe disease activity); csDMARD: conventional*
267   *synthetic Disease-Modifying Antirheumatic Drug; bDMARD: biological Disease-Modifying Antirheumatic Drug*

13

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268   *Quantitative*

269   ▪   Adherence and agreement

270   Twenty-seven patients (57.4%) were able to use the self-monitoring program without additional

271   training, whereas twenty patients (42.6%) attended the instruction classes. With regard to the PROM

272   preferences, RAID was chosen most often, namely 34 times. HAQ and RADAI-5 were chosen 27 and 23

273   times, respectively. Seventeen patients chose to complete one PROM, 21 patients chose to complete

274   two PROMs, and nine patients chose to complete three PROMs. Mean adherence to the

275   predetermined PROM frequency was 68.1%, see table 2. With regard to the agreement between the

276   DAS28 course and PROM values, RAID scored best (from 25 assessments, 17 times a score of 'good',

277   68.0%). RADAI-5, on the other hand, scored 'good' in ten out of seventeen assessments (58.8%), see

278   table 3. Figure 2 shows two examples of assessments regarding the agreement between the DAS28

279   course and PROM values.

280

281   Table 2. Data regarding PROM frequency, PROM scores, and adherences rates, n = 47

Item	n (%)
PROM frequency	
1 week	4 (8.5)
2 weeks	10 (21.3)
4 weeks	31 (66.0)
≥ 6 weeks	2 (4.3)
Number of PROMs to complete, chosen by patient	
One	17 (36.17)
Two	21(44.68)
Three	9 (19.15)
Mean adherence (%) to the predetermined PROM frequency	68.1%

282   *PROM: Patient-Reported Outcome Measure; Adherence to the predefined PROM frequency: calculated by*

283   *dividing the number of completed PROMs by the number of PROM assessments (based on the reminder emails)*

284   *that should have been completed according to the chosen PROM frequency by the patient, times 100*

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286 < Figure 2. Example of a positive (above) and negative (below) rating regarding the PROM-DAS28

287 agreement >

288 Table 3. Agreement (poor or good) between the DAS28 course and disease-specific PROMs (RAID and

289 RADAI-5), assessed in n = 33 patients

PROM	Poor	Good	Total
RAID	8 (32.0%)	17 (68.0%)	25
RADAI-5	7 (41.2%)	10 (58.8%)	17

290 *PROM: Patient-Reported Outcome Measure; RAID: Rheumatoid Arthritis Impact of Disease; RADAI-5:*

291 *Rheumatoid Arthritis Disease Activity Index-5; DAS28 course: Disease Activity Score using 28 joint counts,*

292 *assessed by rheumatologists; Good: DAS28 course and the PROM scores showed the same direction. Poor:*

293 *DAS28 course and PROM scores showed opposite direction*

294

295 *Qualitative*

296 We conducted the focus group discussion and telephone interviews between December 2016 and June

297 2017. The interviews lasted between 24 and 42 minutes, while the focus group discussion lasted one

298 hour and 22 minutes. Six patients attended the focus group discussion, and four patients participated

299 in a telephone interview (five female and five male patients).

300

301 *Patients' experiences regarding the self-monitoring program*

302 Three main themes emerged from the focus group discussion and interviews: knowledge about and

303 insight into disease (activity), patient-professional interaction, and functionality of the program. Five

304 subcategories emerged: Disease (self)management, discussing results with healthcare professionals,

305 technical factors, user interface and PROMs, and patients' suggestions for improvement. Table 4

306 provides an overview of the themes and subcategories regarding the qualitative analysis.

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309   Table 4. Themes and subcategories with regard to the qualitative analysis of patients' experiences

310   with iMonitor

Theme	Subcategory
Knowledge about and insight into disease (activity)	n.a.
Patient-professional interactions	- Disease (self)management - Discussing results with healthcare professionals
Functionality of the program	- Technical factors - User interface and PROMs - Patients' suggestions for improvement

311   *Three main themes and five subcategories emerged from the qualitative analysis. The checklist from Flottorp et*

312   *al.[25] served as a guide for the establishment of the topic guide*

313

314   *Theme I: Knowledge about and insight into disease (activity)*

315   The most cited reason for using the self-monitoring program was that patients gained insight into their

316   (long-term) disease activity course. Most patients indicated that using the program led to more

317   knowledge and awareness about their disease. Some patients reported that they recognized peaks in

318   disease activity earlier and could subsequently prepare for an exacerbation. Patients also mentioned

319   that they became more prudent when noticing a flare. When asked more specifically about patients'

320   experiences with the agreement between their PROM values and DAS28 scores, most patients thought

321   their PROM values were in line with their DAS28.

322   "*By consciously using the program, it was easier to find things about rheumatism and to gain more*

323   *insight into the question 'What is rheumatism?'*"

17

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324   *Theme II: Patient-professional interactions*

325   ▪   Disease (self)management

326   By using the self-monitoring program, most patients felt less dependent on their HCP. Patients

327   appreciated the fact that they were able to influence their own disease management. Overall, patients

328   thought that the self-monitoring program could contribute to a reduction in the number of outpatient

329   consultations.

330

331   *"I can monitor my disease course, keep record of my disease activity in-between consultations, without*

332   *being dependent on the professional"*

333

334   ▪   Discussing results with healthcare professionals

335   Patients emphasized the importance of discussing the results of online monitoring (e.g. PROM values)

336   with their HCP (rheumatologist or nurse). Most of all, they wanted to know if they were 'doing it right'.

337   Some patients expressed the value of discussing their results with their HCP. One patient provided the

338   following scenario: *'I used to look at the back of a computer screen during an outpatient visit. Now, I'm*

339   *looking at the computer screen together with my HCP, sharing and discussing the PROM values and our*

340   *ideas about my treatment'*. Patients who did not discuss their values felt the need to do so in the

341   future.

342

343   *Theme III: Functionality of the program*

344   ▪   Technical factors

345   Barriers regarding the use of the self-monitoring program were mostly related to technical aspects.

346   Some patients had problems with the login system, which hindered them from accessing the website.

347   Regarding the PROM reminder emails: the system generated an email alert at fixed time points (e.g.

348   four-weekly). Some patients noticed that the system generated an alert at unfortunate time points or

349   even no alert at all.

18

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350   ▪   User interface and PROMs

351 Twenty-seven patients joined the instruction classes, which were perceived to be very helpful. Overall,

352 patients were satisfied with the user interface of the program. They reviewed the layout as clear and

353 comprehensible. Some patients experienced difficulties with the content and layout of the PROMs. For

354 example, some patients thought the questions were not specific enough. Furthermore, the program

355 did not use a progress bar and there was no 'Accomplish' sign after completing a PROM. As a result –

356 in case of completing more than one PROM – some patients did not know how many PROMs they had

357 actually completed.

358

359   ▪   Patients' suggestions for improvement

360 Most commonly mentioned suggestions concerned adjustments to clarify PROM values, for example

361 a textbox to type a comment in case of an exacerbation. Additionally, patients provided suggestions

362 concerning the possibility of also having access to their lab values in the self-monitoring program, as

363 well as the possibility of having a more detailed look at a certain time period.

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366 **Discussion**

367 This study collected experiences from patients with IRDs regarding online self-monitoring. Moreover,

368 we assessed adherence to the predefined PROM frequency to measure disease activity and the

369 agreement between the PROMs and the DAS28 course. The qualitative analysis revealed three themes:

370 knowledge about and insight into disease (activity), patient-professional interaction, and functionality

371 of the program. Overall, patients were mainly positive about the program and were willing to continue.

372 Most of them participated for an extended period: mean follow-up duration was almost one year, and

373 mean adherence to the predefined PROM frequency was 68.1%. Patients reported that they gained

374 more knowledge about their disease and felt less dependent on their HCP.

375

376 By self-monitoring disease activity, patients obtained a graphic overview of their PROM values over

377 time, which gave them insight into their disease course. Patients reported that they appreciated both

378 this long-term insight into their disease pattern, and the ability to anticipate on an exacerbation. They

379 also indicated that they gained more knowledge about their disease, they felt better prepared for a

380 consultation, and felt less dependent on their HCP in handling their disease. Literature about self-

381 monitoring in diabetes already showed that knowledge about the disease and self-monitoring are

382 related[10]. Although some knowledge is a prerequisite for self-monitoring, the process of self-

383 monitoring contributes to the further expansion of disease-related knowledge. Adequate disease-

384 related knowledge is important, since it may influence patients' decisions regarding treatment,

385 compliance, and self-management performance,[28] as well as the ability to recognize signs, symptoms,

386 and patterns,[10] which is supported by a study about experiences with telehealth in patients with RA.[29]

387 All of these aspects are essential in shared-decision making,[30] while also being beneficial to the

388 efficiency of consultations. From the perspective of the HCP, it is important to give feedback to the

389 patients about the results of self-monitoring during outpatient consultations, a fact that was

390 emphasized by our study participants during the interviews. Those who had not received feedback

391 about their PROM-values and/or disease activity course were less motivated to continue with the

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392 program. The importance of feedback was emphasized in a study in which patients with early

393 rheumatoid arthritis received visual feedback by their HCP about their disease progression. Compared

394 to patients who received standard care, patients who received feedback showed significant differences

395 regarding disease activity parameters.[31] Obtaining insight into the long-term disease activity course,

396 and being able to anticipate on an exacerbation, might benefit the effectiveness of the delivered care

397 as well. Patients will be able to respond to a deterioration in a timely manner and will have a greater

398 chance to receive the care they need at the right time, resulting in a decrease of the cumulative disease

399 activity. On the other hand, fewer consultations are possible if the disease activity is stable, which will

400 eventually lead to less frequent outpatient visits. That reduction of health care costs can be obtained

401 by introducing patient-report outcomes (PROs) in the follow-up was shown by a study on tele-health

402 in RA. Patients received PRO-based health follow-up and were scheduled for telephone consultations

403 by a rheumatologist or nurse. Similar results regarding disease control were found for the telehealth

404 group compared with conventional follow-up.[32] Studies on self-monitoring in other chronic diseases

405 have already proven its effectiveness, such as better control of blood glucose levels in diabetes,[33 34]

406 reduction in mortality rates in heart failure,[35 36] reductions in blood pressure in hypertension,[37 38] and

407 reductions in thromboembolic events in patients using anticoagulation therapy.[39] The effectiveness of

408 self-monitoring resulted in a reduction in hospital readmissions in patients with hypertension, COPD

409 and heart failure.[40] Patients in our study believed that self-monitoring could lead to a reduction in

410 consultations, although they stressed the need and possibility for contacting the outpatient clinic when

411 necessary. To our knowledge, there are no studies in IRDs on the efficiency of online remote self-

412 monitoring of the disease activity by completing PROMs using an online program on reduction in

413 consultations. Further research will therefore be needed.

414

415 Barriers regarding online self-monitoring were mostly related to the functionality of the online

416 monitoring system. Some patients experienced log-on problems, while others would like to have

417 access in the system to more extensive information about their health status in general (e.g. blood test

21

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418   results). Literature in the field of technology and innovations indicates that factors such as

419   compatibility, complexity, and relative advantage influence the adoption of new innovations.[41]

420   Therefore, a self-monitoring program should be comprehensible and user-friendly and preferably

421   integrated into an existing hospital system. In addition, we recommend screening patients on

422   motivation and computer skills and providing guided practice. We also recommend to let patients

423   choose their own preferred interval and PROM(s). Forcing patients to complete PROMs at predefined

424   intervals set by researchers does not support our idea of self-management and might impede patients'

425   motivation. Some patients chose for weekly self-assessment which might seem to be too frequent for

426   us as healthcare professionals. However, especially in an early or active phase of the disease, this

427   seems to be supportive for some patients. Despite experienced barriers, almost half of the participants

428   reached the end of the study, and the follow-up duration was almost one year. Since there was no real

429   'need' or urgency for self-monitoring in our study, as opposed to blood glucose monitoring in diabetes,

430   for example, reaching complete (100%) adherence was not a realistic option. Even so, adherence to

431   the predetermined PROM frequency was reasonably high. Sending reminders to fill in PROMs was

432   possibly related to these reasonably high rates, and was considered by the patients to be very useful.

433

434   By using qualitative methods we were able to examine the experiences and barriers that influence

435   participation in self-monitoring programs. This resulted in a thorough understanding of the concept of

436   self-monitoring, and guidance for further development. The main limitation of this study was the

437   selective, highly motivated study population. Because of the small study sample, it remains unclear

438   which percentage of the total population will be eligible for self-monitoring. However, the main

439   purpose was to gather experiences about self-monitoring, which were provided by the extensive

440   comments of the patients. Another limitation has to do with the purpose sampling technique, which

441   might have caused selection bias. With regard to difficulties in data interpretation in qualitative

442   research, it remains unclear if we did really grasp what patients were really thinking or feeling. Next to

443   this, the moderator was the main care provider for some patients which might have influenced their

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444 responses. Despite these limitations, we extensively and thoroughly discussed our data several times

445 in order to identify the relevant categories and emerging themes regarding self-monitoring.

446

447 In the present study, patients were willing and able to self-monitor their disease. By monitoring their

448 disease activity at home, they were involved in their own disease management and had individual

449 control and responsibilities. During outpatient visits, patients might be better prepared to interact with

450 their HCP, which will improve shared-decision making, contributing to the concept of personalized

451 care. Self-monitoring – as a prerequisite of self-management – might benefit the cost-effectiveness of

452 outpatient consultations. Efficiency gains are reflected in a reduction in the number of consultations

453 without any increase in costs. At the same time, patient outcomes and patients' satisfaction should

454 either remain stable or increase. This study is a first step toward personalized healthcare and involving

455 the patient in decision making about their disease treatment. Findings from our study were used to

456 implement a self-monitoring program at our outpatient clinic using the Integrated Electronic Patient

457 Record from the hospital.

458 The present study showed the potential of self-monitoring as a first step toward disease self-

459 management. Patients reported that they gained more knowledge, felt less dependent on their HCP,

460 and most of them were able to monitor their disease. Therefore, we believe that self-monitoring can

461 benefit the quality and efficiency of healthcare. Further research will be needed to confirm the cost-

462 effectiveness of self-monitoring.

463

464 **Acknowledgment**

467

468 **Contributors**

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470 Qualitative data collection: LR pretested the topic guide. Focus group discussion: PvR functioned as

471 moderator and LR as observer. Telephone interviews were conducted by LR. Quantitative data

472 collection: PvR and SR (mainly clinical data), whereas LR obtained data derived from the self-

473 monitoring program. Qualitative data analysis: LR was involved as one of the coders during the coding

474 process, together with a research assistant. Provisional categorization of themes: LR and AH. Final

475 version of the categorization of themes and categories: all authors. Quantitative data analysis: all

476 authors. Writing: LR drafted the first version of the manuscript. PvR, AH and SR revised the manuscript.

477 The final manuscript has been seen and approved by all authors.

478

486 **Ethics**

487 The present study fulfills the Helsinki criteria and was approved by the Medical Ethical Committee of

488 the Radboud University Medical Center Nijmegen approved the study (2016-2435) and concluded that

489 no specific obligations were applicable to this research.

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491 **Data**

492 Additional data is available from the corresponding author on reasonable request.

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594   **Figure legends**

595   Figure 1:

596   *Y-axis: 47 patients who participated in the self-monitoring program, each line represents a patient; X-axis: days*
597   *since start of study (different start days possible for patients)*
598

599   Figure 2:

600   *DAS28: Disease Activity Score 28; PROM: Patient-Reported Outcome Measure; RADAI-5: Rheumatoid Arthritis*
601   *Disease Activity Index-5; RAID: Rheumatoid Arthritis Impact of Disease.*
602   *Above: good congruence between PROM-values and DAS28-scores. Below: poor congruence between PROM-*
603   *values and DAS28-scores*
604   *Poor: DAS28 course and PROM scores show opposite direction; Good: DAS28 course and the PROM scores show*
605   *the same direction*

30

Figure 1. Follow-up duration in days of the 47 iMonitor participants

Y-axis: 47 patients who participated in the self-monitoring program, each line represents a patient; X-axis: days since start of study (different start days possible for patients)

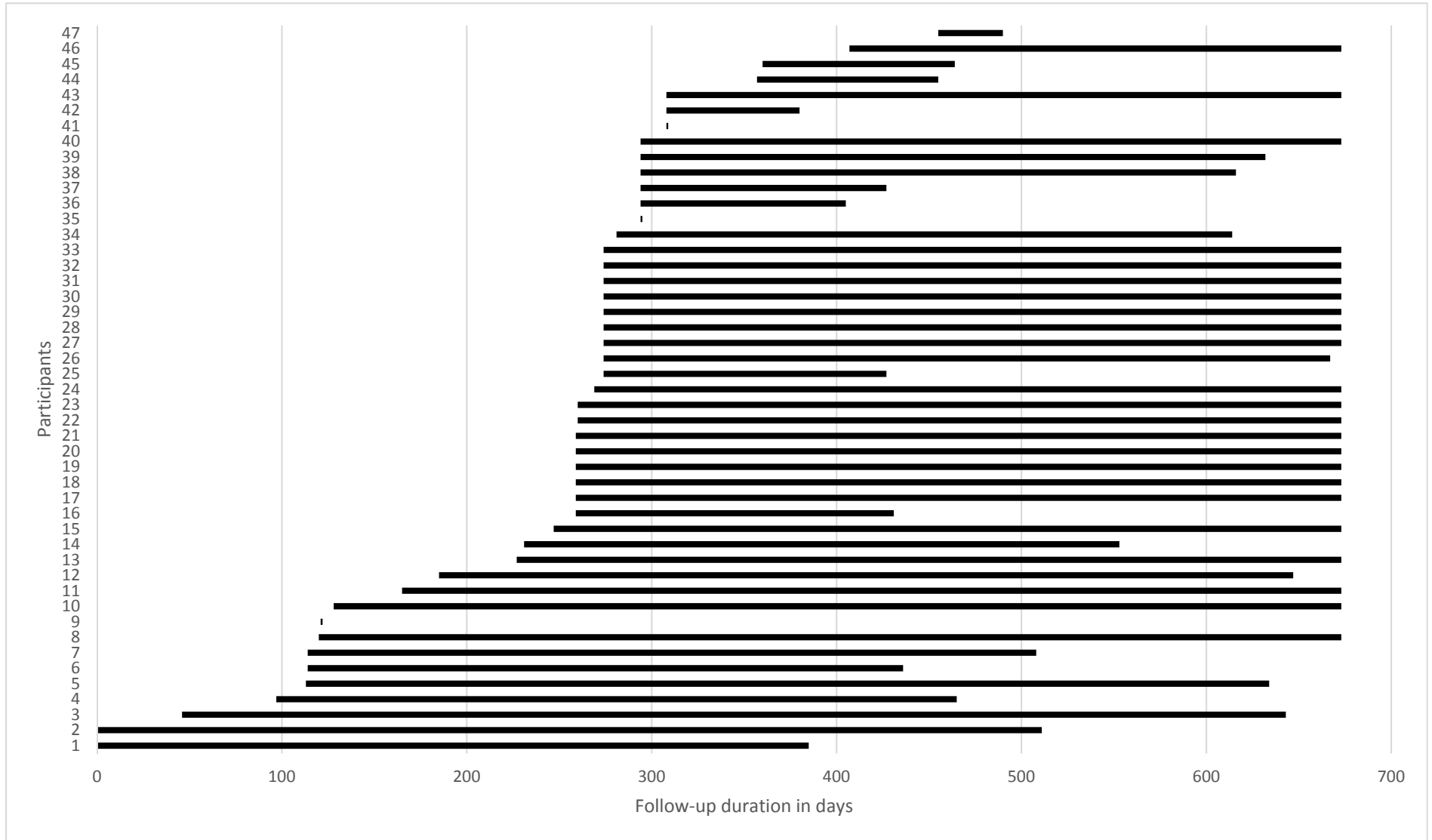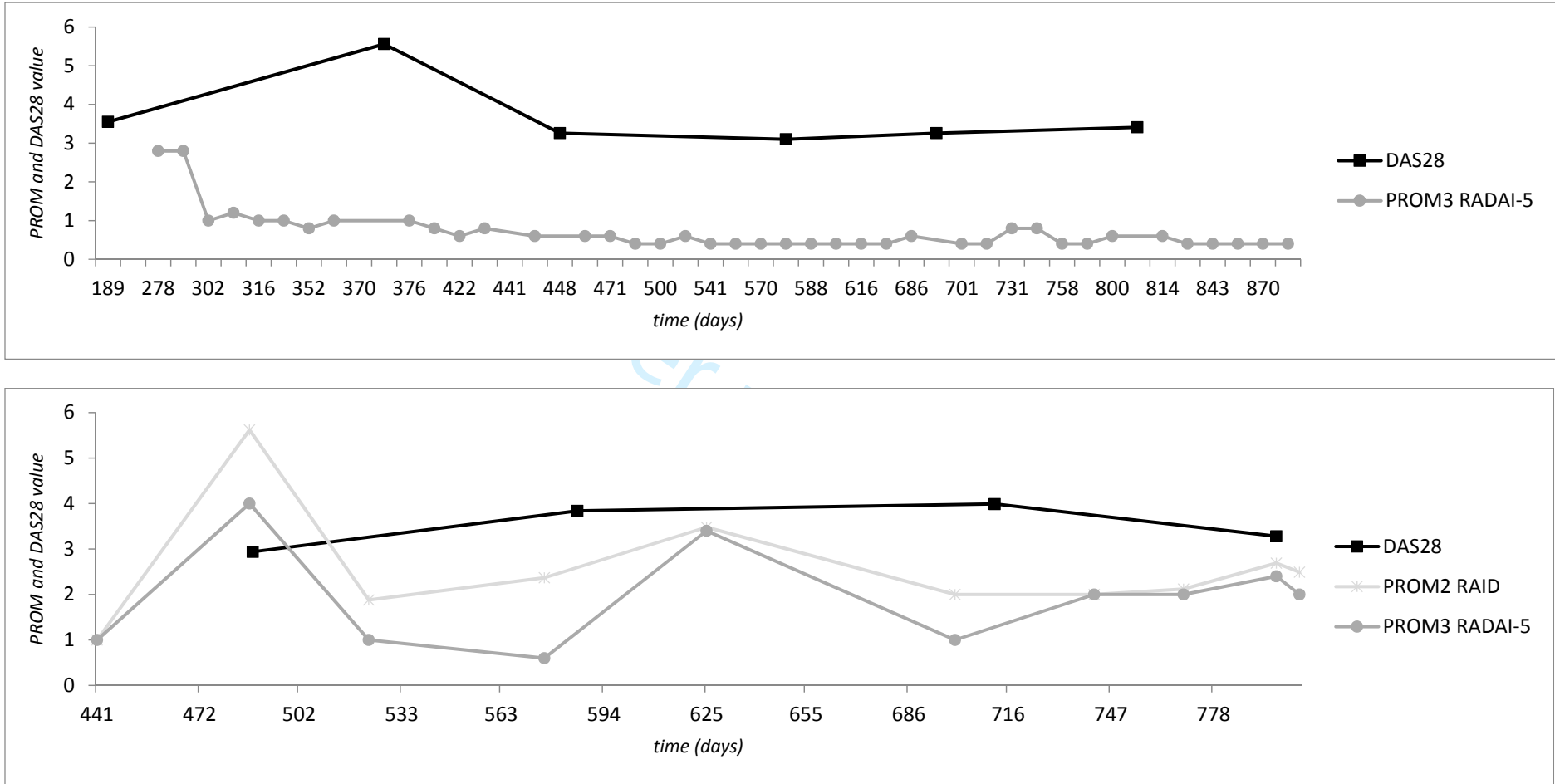Figure 2. Example of a positive (above) and negative (below) rating regarding the agreement between the PROMs and DAS28 course

DAS28: Disease Activity Score 28; PROM: Patient-Reported Outcome Measure; RADAI-5: Rheumatoid Arthritis Disease Activity Index-5; RAID: Rheumatoid Arthritis Impact of Disease.

Above: good congruence between PROM-values and DAS28-scores. Below: poor congruence between PROM-values and DAS28-scores

Poor: DAS28 course and PROM scores show opposite direction; Good: DAS28 course and the PROM scores show the same direction

Appendix

Topic guide: "Patients' experiences regarding online self-monitoring of the disease course"

Guideline related factors

1. Which elements of the program are useful in your opinion, and why? Which are not useful, and why?

2. On what devices are you using the program?

3. What are your experiences with using iMonitor on these devices?

4. What do you think about the lay-out of iMonitor?

5. What do you think about the lay-out of de questionnaires/PROMs?

6. Do you encounter any technical problems while using iMonitor? If yes, which problems have occurred?

7. How did you experience creating a password?

Patient related factors

Motivation

8. For what specific reasons do you use the program?

9. What do you think are the benefits of using iMonitor?

10. Are there any reasons why you should not use the program?

Needs

11. To what specific needs does iMonitor comply?

Skills

12. Which skills are needed to use iMonitor properly according to you?

13. Do you have those skills?

Self-efficacy

14. Do you think you are capable to use iMonitor correctly? Why?

Adherence

You received an email-alert in case a PROM/PROMs could be completed.

15. What are your experiences with receiving those alerts?

16. What do you think about the idea of receiving alerts?

17. To what extent do these email-alerts activate you to complete the PROM/PROMs?

1

Social support

18. Are you supported by others (family, friends, peers) regarding the use of iMonitor?

    If yes: who and to what extent?

19. Do you talk with others about iMonitor? If yes, who?

20. How do you feel about receiving that social support?

Professional interaction

21. Do you/did you discuss the use of iMonitor with your rheumatologist or nurse specialist?

22. If yes, how do you/did you feel about that?

23. In case you attended the instruction class: What is your opinion about this instruction class?

Incentives and resources

Incentives/stimuli

24. In case you kept using the program: what made you keep using the program?

25. Which additional value do you experience by using iMonitor?

2

Knowledge

26. Do you gain more knowledge by using the program?

   a. If yes, how and to what extent?

   b. If no, why not?

Time investment

27. What do you think about the time investment needed in order to use iMonitor?

Capacity for organizational change

28. Do you think that using iMonitor could contribute to a reduction in the number of outpatient

   consultations, and why? Or why not?

29. Do you have any recommendations in order to recruit more patients?

Social, political and legal factors

30. How do you think about the privacy standards regarding the use of iMonitor?

31. Have there been any issues you needed to solve?

Any additional information you want to share with us? Any comments or suggestions?

3

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Patients' experiences regarding self-monitoring of the disease course: an observational pilot study in patients with Inflammatory Rheumatic Diseases

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2 Patients' experiences regarding self-monitoring of the disease course: an observational pilot study in

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36

37   **Abstract**

38   Objectives. Self-monitoring the disease course is a relatively new concept in the management of

39   patients with Inflammatory Rheumatic Diseases (IRDs). The aims of this pilot study were to obtain

40   patients' experiences with online self-monitoring, to assess information about the agreement between

41   the disease course assessed with Patient Reported Outcome Measures (PROMs) and an objectively

42   measured Disease Activity Score by the rheumatologist (DAS28), and to assess adherence to

43   predetermined PROM frequency intervals.

44

45   Design. Observational study using qualitative and quantitative methods.

46   Setting. The rheumatology outpatient clinic of a teaching hospital in the Netherlands (secondary care).

47   Participants: 47 Patients with an IRD who regularly attended the outpatient clinic.

48

49   Methods. Patients completed PROMs by using an online self-monitoring program. Their experiences

50   regarding self-monitoring were qualitatively assessed through a focus group discussion and telephone

51   interviews using a thematic analysis approach. Adherence to the predefined PROM frequency

52   (completed PROM assessments within the predetermined frequency) and the agreement between the

53   DAS28 course and PROM values (Rheumatoid Arthritis Disease Activity Index-5 (RADAI-5) and the

54   Rheumatoid Arthritis Impact of Disease (RAID)) were quantitatively assessed using descriptives.

55

56   Results. Forty-seven patients participated, most of them diagnosed with RA (n = 38, 80.9%). Three

57   themes were identified: knowledge about and insight into disease (activity), patient-professional

58   interaction, and functionality of the program. Mean adherence to the predetermined PROM frequency

59   was 68.1%. The RAID showed the best agreement with the DAS28 course. Mean participation time was

60   350 days.

2

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61

62   Conclusion. Patients were predominantly positive about online self-monitoring. They indicated that

63   they gained more knowledge about their disease, felt less dependent on the healthcare professional,

64   and valued the insight into their long-term disease course. Barriers were mostly related to technical

65   factors. Patients were able to and willing to self-monitor their disease, which could contribute to a

66   more efficient allocation of outpatient consultations in the future.

67

68

3

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69   **Article summary**

70

71   Strengths and limitations of this study:

72

73   • A strength of this study is the use of both qualitative and quantitative research methods,

74   providing a rich description of factors associated with self-monitoring

75   • Patients were closely involved during the development stage, execution, and evaluation

76   stage of this study

77   • Using validated Patient Reported Outcome Measures (PROMs) assessing disease activity and

78   disease impact allowed us to compare these PROM scores with objective, health professional

79   assessed scores

80   • Due to the selective and small study population it is not clear which percentage of the total

81   population with IRD is willing to and able to self-monitor the disease course

82

4

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83 **Introduction**

84 In chronic care, there is a tendency toward personalized healthcare. Patients have become more

85 empowered and are increasingly involved in the planning and development of healthcare.[1-4] There is a

86 shift from a paternalistic model (in which the doctor is dominant and believes that patients need to be

87 guided through the decision making process) to a shared-decision making model (in which doctor and

88 patient make mutual, collaborative decisions). This shift requires an engaged patient who takes

89 responsibilities regarding day-to-day disease management.[5-8] As a result of this shift, new roles for

90 both patients and healthcare professionals (HCPs) have arisen. An example of what this new role

91 entails for a patient is self-monitoring, in which a patient undertakes self-measurement of vital signs,

92 symptoms, behavior, or psychological well-being through Patient-Reported Outcome Measures

93 (PROMs).[9 10] In some patients with Inflammatory Rheumatic Diseases (IRDs) such as Rheumatoid

94 Arthritis (RA), Psoriatic Arthritis (PsA), or Ankylosing Spondylitis (AS), self-monitoring may gradually

95 replace the traditional monitoring by HCPs.[11] Examples of disease-specific and validated PROMs in IRDs

96 that can be used in self-monitoring are the Rheumatoid Arthritis Impact of Disease[12 13] (RAID), which

97 measures disease impact, and the Rheumatoid Arthritis Disease Activity Index-5[14-16] (RADAI-5), which

98 measures disease activity. An example of a general or non-specific PROM is the Health Assessment

99 Questionnaire (HAQ), measuring functional status.

100 There are however also other reasons why self-monitoring in patients with IRD has gained

101 more interest. Usual care in patients with IRDs is primarily aimed at suppressing disease activity, in

102 order to prevent structural damage.[17 18] The disease activity can be measured using a composite index,

103 the Disease Activity Score using 28 joint counts[19], which measures tender and swollen joint counts,

104 acute phase response, and a patient's general health assessment. The Treat-to-Target Task Force

105 recommends rheumatologists to monthly assess patients with moderate or high disease activity, and

106 patients with controlled and low disease activity every three to six months.[20] In practice, however,

107 these frequencies are not always met for various reasons. This strategy causes time constraints and a

108 growing workload among rheumatologists, making it not manageable for all rheumatologists to comply

5

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109   fully to the frequent assessments.[21] Another reason is connected to the aging population. The number

110   and proportion of patients with IRDs aged 65 and over will increase in the near future.[22] Self-

111   monitoring of the disease course using disease-specific PROMs such as RAID or RADAI-5 could prove

112   to be a solution in diminishing the number of consultations.[23] As disease activity can only be objectively

113   assessed during outpatient consultations, it remains unclear what happens to the disease activity in-

114   between consultations. Fluctuations and peeks in disease activity are easily missed or they remain

115   unnoticed, which could have disastrous consequences regarding joint damage.[17] Self-monitoring might

116   also give a better insight into these fluctuations of disease activity in-between outpatient clinical

117   consultations. Moreover, some patients visit their rheumatologist while their disease activity is under

118   control, thereby contributing to unnecessary outpatient consultations. Summarizing, self-monitoring

119   of disease activity in IRDs as a first step toward personalized healthcare enables patients as well as

120   HCPs to get insight into the disease activity course over time. Moreover, it may lead to a more

121   consistent reporting in the long term and may contribute to optimizing the number, timing, and

122   efficiency of consultations.[11 23] By completing PROMs, patients who need further medical attention can

123   be identified and receive additional medical attention. Moreover, completion of a PROM will help a

124   patient to prepare for a visit and it could improve the communication between physician and patient.[24]

125   [25]

126   In the present study an online self-monitoring program was pilot-tested in order to test the

127   feasibility of self-monitoring before implementation of a self-monitoring program in daily clinical

128   practice. The aims of this study were to obtain patients' experiences regarding online self-monitoring,

129   to assess the agreement between the disease course assessed with disease-specific PROMs (RAID and

130   RADAI-5) and an objectively measured disease activity score (DAS28) by the rheumatologist, and to

131   assess the adherence to predetermined PROM frequency intervals.

132

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133 **Methods**

134 *Study design*

135 This observational pilot study using quantitative and qualitative research methods, was conducted at

136 a teaching hospital in Uden (the Netherlands) at the rheumatology outpatient clinic from 6 July 2015

137 until 9 May 2017.

138

139 *Inclusion criteria*

140 In order to be eligible for this study, patients had to be diagnosed with an IRD according to the

141 ACR/EULAR criteria.[26] Furthermore, they needed to have an electronic device (laptop/PC, tablet or

142 Smartphone) with access to the Internet, and they needed to be able to sufficiently read and write

143 Dutch. Patient inclusion started in July 2015 and we included the last patient in October 2016.

144

145 *Follow-up duration*

146 Patients were able to withdraw from the program at any time point. We defined early study

147 termination in two manners: when a patient reported to withdraw from the self-monitoring program,

148 this was evaluated as the end date. Some patients did not report dropping out of the study but did

149 stop completing PROM(s). End of study in these cases was set by adding the interval time to the date

150 the last PROM was filled in. For example, a patient with a four-week PROM frequency (28 days)

151 completed the last PROM on 1 March 2017. For this patient, end of study date was set on 29 March

152 2017.

153

154 *Self-monitoring program*

155 iMonitor, the online self-monitoring program tested in this study, was developed by Pfizer.[27] The

156 program was accessible through a laptop, tablet or Smartphone by filling in a user name, password,

157 and pin code. The program complied with the required privacy standards. Because the program was

158 intended to stimulate patient involvement, personalized healthcare and patient self-management,

7

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159   patients selected their preferred PROM(s) and PROM frequency (one-, two-, four-, six- or eight-weekly)

160   in advance and the system generated an email-alert for filling in a PROM (or PROMs) accordingly.

161   Patients were able to complete one or more PROMs within a timeframe of 24 hours. They could send

162   a message to the HCPs in case of questions or notifications by using the message option. In case of

163   urgent matters, they could contact the outpatient clinic by telephone.

164

165   *Patient-Reported Outcome Measures (PROMs)*

166   Available disease-specific PROMs for patients with RA were the RAID and the RADAI-5, measuring

167   disease impact (0-10; 10 = severe impact of disease activity) and disease activity (0-10; 10 = severe

168   disease activity). Patients with AS could fill in the disease-specific Bath Ankylosing Spondylitis Disease

169   Activity Index (BASDAI), measuring disease activity (0-10; 10 = severe disease activity), and/or the Bath

170   Ankylosing Spondylitis Functional Index (BASFI), measuring physical function (0-10; 10 = severe

171   functional limitation). The HAQ, general PROM that measures physical function, was available for all

172   patients (0-3; 3 = severe disability). Patients could opt to assess one to three PROMs. Completion of all

173   PROMs took about 5 minutes. After completion, the PROM scores were subsequently displayed in a

174   graph. Additionally, DAS28 scores (0-10; remission: DAS28 <2.6, low disease activity: ≥ 2.6 DAS28 < 3.2,

175   moderate disease activity: ≥ 3.2 DAS28 ≤5.1, high disease activity: DAS28 > 5.1) could be added to the

176   graph by the HCP. These DAS28 scores were obtained by the HCPs during outpatient consultations and

177   were kept in the electronic medical files from the hospital.

178

179   *Procedure - Recruitment*

180   Patients were informed about this pilot study and recruited in several ways. Firstly, we used purposive

181   sampling: rheumatologists themselves asked possible suitable patients to participate during

182   outpatient consultations during the entire study period. Secondly, during general information

183   meetings at the hospital, patients were informed about the study and were able to sign up. Lastly,

184   leaflets about the study were available in the waiting room and patients were informed about the

8

185 study through the hospital's website. Patients received a manual containing information regarding

186 access to and use of the program. However, a substantial number needed additional training, which

187 was provided by instruction classes. After patients had been instructed how to use the program, they

188 could indicate which PROM(s) they preferred to fill in by showing them the paper versions. Moreover,

189 they were asked to indicate their desired frequency option. Patients who agreed to take part in the

190 study were asked to sign a consent form. During the regular outpatient consultations, rheumatologists

191 were expected to provide feedback to the patient about the patient's disease course and PROM

192 results.

193

194 *Data collection and analysis*

195 Quantitative methods

196 ▪ Adherence and agreement

197 Firstly, we determined adherence to the predetermined PROM frequency by assessing whether a

198 patient had completed (yes or no) the PROM(s) in the predetermined time interval. Adherence was

199 calculated as the number of completed assessments by the patient divided by the number of PROM

200 assessments that should have been completed according to the chosen interval of the patient times

201 100%. For example, a patient with a weekly PROM frequency participated for one year. This patient

202 should have received 52 email-alerts, so 52 PROM assessments should have been completed. This

203 patient completed 40 PROM assessments, so adherence is (40/52*100 =) 76.9%. Secondly, we

204 determined the agreement between the DAS28 course and PROM values. Two researchers (LR and

205 PvR) independently assessed agreement by comparing the DAS28 course with the corresponding

206 PROM-value(s) from the RAID and/or RADAI-5 using two categories (poor and good) and discussed

207 discrepancies. The RAID and the RADAI-5 were used, because these two disease-specific PROMs

208 measure disease impact and activity, whereas the HAQ is non-disease specific. 'Good' was used in

209 cases where the DAS28 course and the PROM scores showed the same direction (i.e. the DAS28 course

210 increased and PROM scores as well). 'Poor' was used in cases where the DAS28 course and PROM

9

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211 scores showed opposite directions (the DAS28 course increased and PROM scores decreased (or the

212 other way around). Data from patients with at least three PROM values (falling within a fourteen-day-

213 window with DAS28 assessment) were assessed.

214

215 Qualitative methods

216 Patients' experiences with the self-monitoring program were obtained via a focus group and semi-

217 structured interviews. The purpose of the focus group and interviews was to gain insight into relevant

218 factors that might hinder or facilitate patients using the self-monitoring program. The checklist from

219 Flottorp et al.[28] served as an inspiration for a semi-structured topic guide (see appendix). Relevant

220 domains for our topic guide were: program factors; patient factors; professional-patient interaction

221 factors; and resources. Prior to the start of the focus group discussion we conducted a telephone

222 interview with one patient to check the appropriateness of the topic guide and to check whether the

223 questions were clear. During the focus group discussion, an experienced moderator (PvR) guided the

224 discussion. Patients unable to attend the focus group were interviewed by telephone, using the same

225 topic guide. All participating patients had at least six months experience with the self-monitoring

226 program.

227

228 *Qualitative analysis*

229 The interviews and focus group discussion were recorded. The recordings were and transcribed ad

230 verbum by an independent agency. One of the researchers (LR) and a research assistant independently

231 coded the transcripts to increase intercoder reliability. They used the method 'thematic analysis' in

232 which the codes were derived from the data with the purpose to describe relevant factors regarding

233 self-monitoring and to identify categories and themes. A constant comparative method was used for

234 the analysis of the emerging themes. Any discrepancies in the analysis were discussed until consensus

235 was reached[29]. Afterwards, two researchers (LR and AH) agreed on a provisional categorization and

236 overarching themes. These categories and overarching themes were also discussed with a third and

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237   fourth researcher (SR and PvR). The COnsolidated criteria for REporting Qualitative research (COREQ)

238   checklist[30] was mainly used as guidance for the reporting of our qualitative research. We conducted

239   coding and analysis by using a qualitative software program (Atlas.ti).

240

241   *Patient and public involvement*

242   Firstly, patient involvement was needed during the establishment of the topic guide, which was pre-

243   tested among one patient in order to check if the questions were comprehensible and clear. Secondly,

244   patients were encouraged to give suggestions and comments regarding the use of the program during

245   the entire study period. This feedback was used as input for the implementation of a revised version

246   of the program at a later stage. Lastly, the study participants exchanged their experiences with the

247   self-monitoring program with other patients (users and non-users) during research meetings at the

248   hospital.

249

250   **Results**

251   *Study population*

252   In this pilot study, slightly more women than men participated (n=27; 57.4%). Mean($\pm$) age was

253   57.3(10.7) years. Most patients (n=38) were diagnosed with RA (80.9%), while nine patients were

254   diagnosed with a SpA (eight patients with PsA, and one patient with AS). Other baseline characteristics

255   are given in Table 1. Of over 1800 patients with an IRD, we included 47 patients during the study period.

256   Two patients eventually signed the informed consent form but did not complete any PROMs and were

257   withdrawn from the study. An overview of the follow-up duration is presented in Figure 1. In total,

258   twenty-three patients participated from the start (different start dates were possible) until the end of

259   the study (48.9%). The follow-up duration of the 45 patients who completed PROMs varied between

260   14 and 597 days, with a mean of 350 days.

261

262   < Figure 1. Follow-up duration in days of the 47 iMonitor participants >

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263   Table 1. Baseline characteristics of the 47 patients using the self-monitoring program

264

Characteristics	Rheumatoid arthritis, n = 38	SpA group, n = 9
Patient and disease characteristics		
Age, years, mean (SD)	57.74 (11.17)	55.67 (8.69)
Female, n (%)	20 (52.6%)	7 (77.8%)
Disease duration, years, mean (SD)	8.08 (4.74)	9.89 (7.25)
DAS28-score, mean (SD)	3.19 (1.25)	n.a.
Educational level		
Low, n (%)	12 (34.3)	3 (37.5)
Middle, n (%)	11 (31.4)	3 (37.5)
High, n (%)	12 (34.3)	2 (25.0)
Baseline PROM-values		
HAQ [0.00-3.00] (n=27), mean, SD, range	0.78 (0.61) [0.00;2.38]	0.98 (0.60) [0.13;1.88]
RADAI-5 [0.00 – 10.00] (n=24), mean, SD, range	3.49 (2.32) [0.00;7.40]	n.a.
RAID [0.00 – 10.00) (n=35) mean, SD, range	3.47 (2.28) [0.00;7.61]	n.a

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BASFI [0.00 – 10.00] (n=1), mean, SD	n.a.	5.05
BASDAI [0.00 – 10.00] (n=1), mean, SD	n.a.	4.60
Medication use		
csDMARD, n (%)	36 (94.7%)	8 (88.9%)
bDMARD, n (%)	12 (32.0%)	3 (33.3%)

265 *SpA: Spondylarthropathy; HAQ: Health Assessment Questionnaire (3 = severe disability); RADAI-5: Rheumatoid Arthritis Disease Activity Index-5 (10 = severe disease activity);*

266 *RAID: Rheumatoid Arthritis Impact of Disease (10 = severe impact of disease activity); BASFI: Bath Ankylosing Spondylitis Functional Index (10 = severe functional limitation);*

267 *BASDAI: Bath Ankylosing Spondylitis Disease Activity Index (10 = severe disease activity); csDMARD: conventional synthetic Disease-Modifying Antirheumatic Drug; bDMARD:*

268 *biological Disease-Modifying Antirheumatic Drug*

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269　*Quantitative*

270　　　▪　Adherence and agreement

271　Twenty-seven patients (57.4%) were able to use the self-monitoring program without additional

272　training, whereas twenty patients (42.6%) attended the instruction classes. With regard to the PROM

273　preferences, RAID was chosen most often, namely 34 times. HAQ and RADAI-5 were chosen 27 and 23

274　times, respectively. Seventeen patients chose to complete one PROM, 21 patients chose to complete

275　two PROMs, and nine patients chose to complete three PROMs. Mean adherence to the

276　predetermined PROM frequency was 68.1%, see table 2. With regard to the agreement between the

277　DAS28 course and PROM values, RAID scored best (from 25 assessments, 17 times a score of 'good',

278　68.0%). RADAI-5, on the other hand, scored 'good' in ten out of seventeen assessments (58.8%), see

279　table 3. Figure 2 shows two examples of assessments regarding the agreement between the DAS28

280　course and PROM values.

281

282　Table 2. Data regarding PROM frequency, PROM scores, and adherences rates, n = 47

Item	n (%)
PROM frequency	
1 week	4 (8.5)
2 weeks	10 (21.3)
4 weeks	31 (66.0)
≥ 6 weeks	2 (4.3)
Number of PROMs to complete, chosen by patient	
One	17 (36.17)
Two	21 (44.68)
Three	9 (19.15)
Mean adherence (%) to the predetermined PROM frequency	68.1%

283　*PROM: Patient-Reported Outcome Measure; Adherence to the predefined PROM frequency: calculated by*

284　*dividing the number of completed PROMs by the number of PROM assessments (based on the reminder emails)*

285　*that should have been completed according to the chosen PROM frequency by the patient, times 100*

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287 < Figure 2. Example of a positive (above) and negative (below) rating regarding the agreement between

288 the PROMs and DAS28 course >

289 Table 3. Agreement (poor or good) between the DAS28 course and disease-specific PROMs (RAID and

290 RADAI-5), assessed in n = 33 patients

PROM	Poor	Good	Total
RAID	8 (32.0%)	17 (68.0%)	25
RADAI-5	7 (41.2%)	10 (58.8%)	17

291 *PROM: Patient-Reported Outcome Measure; RAID: Rheumatoid Arthritis Impact of Disease; RADAI-5:*

292 *Rheumatoid Arthritis Disease Activity Index-5; DAS28 course: Disease Activity Score using 28 joint counts,*

293 *assessed by rheumatologists; Good: DAS28 course and the PROM scores showed the same direction. Poor:*

294 *DAS28 course and PROM scores showed opposite direction*

295

296 *Qualitative*

297 We conducted the focus group discussion and telephone interviews between December 2016 and June

298 2017. The interviews lasted between 24 and 42 minutes, while the focus group discussion lasted one

299 hour and 22 minutes. Six patients attended the focus group discussion, and four patients participated

300 in a telephone interview (five female and five male patients).

301

302 *Patients' experiences regarding the self-monitoring program*

303 Three main themes emerged from the focus group discussion and interviews: knowledge about and

304 insight into disease (activity), patient-professional interaction, and functionality of the program. Five

305 subcategories emerged: Disease (self)management, discussing results with healthcare professionals,

306 technical factors, user interface and PROMs, and patients' suggestions for improvement. Table 4

307 provides an overview of the themes and subcategories regarding the qualitative analysis.

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310 Table 4. Themes and subcategories with regard to the qualitative analysis of patients' experiences

311 with iMonitor

Theme	Subcategory
Knowledge about and insight into disease (activity)	n.a.
Patient-professional interactions	- Disease (self)management - Discussing results with healthcare professionals
Functionality of the program	- Technical factors - User interface and PROMs - Patients' suggestions for improvement

312 *Three main themes and five subcategories emerged from the qualitative analysis. The checklist from Flottorp et*

313 *al.[28] served as a guide for the establishment of the topic guide*

314

315 *Theme I: Knowledge about and insight into disease (activity)*

316 The most cited reason for using the self-monitoring program was that patients gained insight into their

317 (long-term) disease activity course. Most patients indicated that using the program led to more

318 knowledge and awareness about their disease. Some patients reported that they recognized peaks in

319 disease activity earlier and could subsequently prepare for an exacerbation. Patients also mentioned

320 that they became more prudent when noticing a flare. When asked more specifically about patients'

321 experiences with the agreement between their PROM values and DAS28 scores, most patients thought

322 their PROM values were in line with their DAS28. One 55-year old male patient noted: "*By consciously*

323 *using the program, it was easier to find things about rheumatism and to gain more insight into the*

324 *question 'What is rheumatism?'*"

17

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325 *Theme II: Patient-professional interactions*

326 ▪ Disease (self)management

327 By using the self-monitoring program, most patients felt less dependent on their HCP. Patients

328 appreciated the fact that they were able to influence their own disease management. Overall, patients

329 thought that the self-monitoring program could contribute to a reduction in the number of outpatient

330 consultations.

331

332 *"I can monitor my disease course, keep record of my disease activity in-between consultations, without*

333 *being dependent on the professional"* (47-year old female patient)

334

335 ▪ Discussing results with healthcare professionals

336 Patients emphasized the importance of discussing the results of online monitoring (e.g. PROM values)

337 with their HCP (rheumatologist or nurse). Most of all, they wanted to know if they were 'doing it right'.

338 Some patients expressed the value of discussing their results with their HCP. One 55-year old male

339 patient provided the following scenario: *"I used to look at the back of a computer screen during an*

340 *outpatient visit. Now, I'm looking at the computer screen together with my HCP, sharing and discussing*

341 *the PROM values and our ideas about my treatment"*. Patients who did not discuss their values felt the

342 need to do so in the future.

343

344 *Theme III: Functionality of the program*

345 ▪ Technical factors

346 Barriers regarding the use of the self-monitoring program were mostly related to technical aspects.

347 Some patients had problems with the login system, which hindered them from accessing the website.

348 Regarding the PROM reminder emails: the system generated an email alert at fixed time points (e.g.

349 four-weekly). Some patients noticed that the system generated an alert at unfortunate time points or

350 even no alert at all.

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351 ▪ User interface and PROMs

352 Twenty-seven patients joined the instruction classes, which were perceived to be very helpful. Overall,

353 patients were satisfied with the user interface of the program. They reviewed the layout as clear and

354 comprehensible. Some patients experienced difficulties with the content and layout of the PROMs. For

355 example, some patients thought the questions were not specific enough. Furthermore, the program

356 did not use a progress bar and there was no 'Accomplish' sign after completing a PROM. As a result –

357 in case of completing more than one PROM – some patients did not know how many PROMs they had

358 actually completed.

359

360 ▪ Patients' suggestions for improvement

361 Most commonly mentioned suggestions concerned adjustments to clarify PROM values, for example

362 a textbox to type a comment in case of an exacerbation. Additionally, patients provided suggestions

363 concerning the possibility of also having access to their lab values in the self-monitoring program, as

364 well as the possibility of having a more detailed look at a certain time period.

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367 **Discussion**

368 This study collected experiences from patients with IRDs regarding online self-monitoring. Moreover,

369 we assessed adherence to the predefined PROM frequency to measure disease activity and the

370 agreement between the PROMs and the DAS28 course. The qualitative analysis revealed three themes:

371 knowledge about and insight into disease (activity), patient-professional interaction, and functionality

372 of the program. Overall, patients were mainly positive about the program and were willing to continue.

373 Most of them participated for an extended period: mean follow-up duration was almost one year.

374 Mean adherence to the predefined PROM frequency was 68.1%, and RAID showed best agreement

375 with the objectively measured DAS28. Patients reported that they gained more knowledge about their

376 disease and felt less dependent on their HCP.

377

378 By self-monitoring disease activity, patients obtained a graphic overview of their PROM values over

379 time, which gave them insight into their disease course. Patients reported that they appreciated both

380 this long-term insight into their disease pattern, and the ability to anticipate on an exacerbation. They

381 also indicated that they gained more knowledge about their disease, they felt better prepared for a

382 consultation, and felt less dependent on their HCP in handling their disease. Literature about self-

383 monitoring in diabetes already showed that knowledge about the disease and self-monitoring are

384 related[10]. Although some knowledge is a prerequisite for self-monitoring, the process of self-

385 monitoring contributes to the further expansion of disease-related knowledge. Adequate disease-

386 related knowledge is important, since it may influence patients' decisions regarding treatment,

387 compliance, and self-management performance,[31] as well as the ability to recognize signs, symptoms,

388 and patterns,[10] which is supported by a study about experiences with telehealth in patients with RA.[32]

389 All of these aspects are essential in shared-decision making,[33] while also being beneficial to the

390 efficiency of consultations. From the perspective of the HCP, it is important to give feedback to the

391 patients about the results of self-monitoring during outpatient consultations, a fact that was

392 emphasized by our study participants during the interviews. Those who had not received feedback

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393 about their PROM-values and/or disease activity course were less motivated to continue with the

394 program. The importance of feedback was emphasized in a study in which patients with early

395 rheumatoid arthritis received visual feedback by their HCP about their disease progression. Compared

396 to patients who received standard care, patients who received feedback showed significant differences

397 regarding disease activity parameters.[34] Obtaining insight into the long-term disease activity course,

398 and being able to anticipate on an exacerbation, might benefit the effectiveness of the delivered care

399 as well. Patients will be able to respond to a deterioration in a timely manner and will have a greater

400 chance to receive the care they need at the right time, resulting in a decrease of the cumulative disease

401 activity. On the other hand, fewer consultations are possible if the disease activity is stable, which will

402 eventually lead to less frequent outpatient visits. That reduction of health care costs can be obtained

403 by introducing patient-report outcomes (PROs) in the follow-up was shown by a study on tele-health

404 in RA. Patients received PRO-based health follow-up and were scheduled for telephone consultations

405 by a rheumatologist or nurse. Similar results regarding disease control were found for the telehealth

406 group compared with conventional follow-up.[35] Studies on self-monitoring in other chronic diseases

407 have already proven its effectiveness, such as better control of blood glucose levels in diabetes,[36 37]

408 reduction in mortality rates in heart failure,[38 39] reductions in blood pressure in hypertension,[40 41] and

409 reductions in thromboembolic events in patients using anticoagulation therapy.[42] The effectiveness of

410 self-monitoring resulted in a reduction in hospital readmissions in patients with hypertension, COPD

411 and heart failure.[43] Patients in our study believed that self-monitoring could lead to a reduction in

412 consultations, although they stressed the need and possibility for contacting the outpatient clinic when

413 necessary. To our knowledge, there are no studies in IRDs on the efficiency of online remote self-

414 monitoring of the disease activity by completing PROMs using an online program on reduction in

415 consultations. Further research will therefore be needed.

416

417 Barriers regarding online self-monitoring were mostly related to the functionality of the online

418 monitoring system. Some patients experienced log-on problems, while others would like to have

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419 access in the system to more extensive information about their health status in general (e.g. blood test

420 results). Despite these barriers, almost half of the participants reached the end of the study, and the

421 follow-up duration was almost one year. Literature in the field of technology and innovations indicates

422 that factors such as compatibility, complexity, and relative advantage influence the adoption of new

423 innovations.[44] Therefore, a self-monitoring program should be comprehensible and user-friendly and

424 preferably integrated into an existing hospital system. In addition, we recommend screening patients

425 on motivation and computer skills and providing guided practice. We also recommend to let patients

426 choose their own preferred interval and PROM(s). Forcing patients to complete PROMs at predefined

427 intervals set by researchers does not support our idea of self-management and might impede patients'

428 motivation. Some patients opted for weekly self-assessments, which might seems to be too frequent

429 for us as healthcare professionals. However, especially in an early or active phase of the disease, this

430 seems to provide some measure of support for some patients. Patients were willing and able to self-

431 monitor their disease. The mean adherence to the predetermined PROM frequency was reasonably

432 high: 68.1%. This could be partly explained by system-related factors such as the reminders, which

433 were considered very useful in encouraging patients to complete the questionnaire. Next to this,

434 patient-related factors such as intrinsic motivation might also have influenced this percentage. Since

435 there was no real 'need' or urgency for self-monitoring in our study, as opposed to blood glucose

436 monitoring in diabetes, for example, reaching complete (100%) adherence was not a realistic option.

437 Both the RAID and RADAI-5 had acceptable agreements with the DAS28, 68.0% and 58.8% respectively.

438 Due to the relatively small number of patients no conclusion can be drawn which PROM should be

439 used to self-monitor the disease course.

440

441 By using qualitative methods we were able to examine the experiences and barriers that influence

442 participation in self-monitoring programs. This resulted in a thorough description of factors related to

443 self-monitoring, and guidance for further development of appropriate tools. The main limitation of this

444 study was the selective, highly motivated study population due to the purpose sampling. Because of

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445 the small study sample, it remains unclear which percentage of the total population will be eligible for

446 self-monitoring. However, the main purpose was to gather experiences about self-monitoring, which

447 were provided by the extensive comments of the patients. With regard to difficulties in data

448 interpretation in qualitative research, it remains unclear whether we actually truly grasped what

449 patients were really thinking or feeling. Interpretations might have been influenced by the professional

450 backgrounds and theoretical perspectives of the researchers. However, the coding process was done

451 together with a collaborator who did not have a scientific background. Another limitation is connected

452 to the fact that the moderator was the main care provider for some patients which might have

453 influenced their responses. Despite these limitations, we extensively and thoroughly discussed our

454 data several times in order to identify the relevant categories and emerging themes regarding self-

455 monitoring.

456

457 By monitoring their disease activity at home, patients were involved in their own disease management

458 and had individual control and responsibilities. During outpatient visits, patients might be better

459 prepared to interact with their HCP, which will improve shared-decision making, contributing to the

460 concept of personalized care. Self-monitoring – as a prerequisite of self-management – might benefit

461 the cost-effectiveness of outpatient consultations. Efficiency gains are reflected in a reduction in the

462 number of consultations without any increase in costs. At the same time, patient outcomes and

463 patients' satisfaction should either remain stable or increase. This study is a first step toward

464 personalized healthcare and involving the patient in decision making about their disease treatment.

465 Findings from our study were used to implement a self-monitoring program at our outpatient clinic

466 using the Integrated Electronic Patient Record from the hospital.

467 The present study showed the potential of self-monitoring as a first step toward disease self-

468 management. Patients reported that they gained more knowledge, felt less dependent on their HCP,

469 and most of them were able to monitor their disease. Therefore, we believe that self-monitoring can

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470 benefit the quality and efficiency of healthcare. Further research will be needed to confirm the cost-

471 effectiveness of self-monitoring.

472

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475 would also like to thank Pfizer for getting the opportunity to test iMonitor.

476

477 **Contributors**

478 Study acquisition: PvR. Conception and design: all authors. Obtaining ethical approval: LR.

479 Qualitative data collection: LR pretested the topic guide. Focus group discussion: PvR functioned as

480 moderator and LR as observer. Telephone interviews were conducted by LR. Quantitative data

481 collection: PvR and SR (mainly clinical data), whereas LR obtained data derived from the self-

482 monitoring program. Qualitative data analysis: LR was involved as one of the coders during the coding

483 process, together with a research assistant. Provisional categorization of themes: LR and AH. Final

484 version of the categorization of themes and categories: all authors. Quantitative data analysis: all

485 authors. Writing: LR drafted the first version of the manuscript. PvR, AH and SR revised the manuscript.

486 The final manuscript has been seen and approved by all authors.

487

488 **Conflicts of interest**

489 This study was partly funded by Pfizer (pharmaceutical company). Pfizer was able to access data

490 available from iMonitor. Pfizer was not involved in any medical policy related to the study participants.

491

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494

495 **Ethics**

24

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496   The present study fulfills the Helsinki criteria and was approved by the Medical Ethical Committee of

497   the Radboud University Medical Center Nijmegen approved the study (2016-2435) and concluded that

498   no specific obligations were applicable to this research.

499

500   **Data**

501   (Anonymous) data are available upon reasonable request by contacting the corresponding author by

502   email.

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610 **Figure legends**

611 Figure 1:

612 *Y-axis: 47 patients who participated in the self-monitoring program, each line represents a patient; X-axis: days*
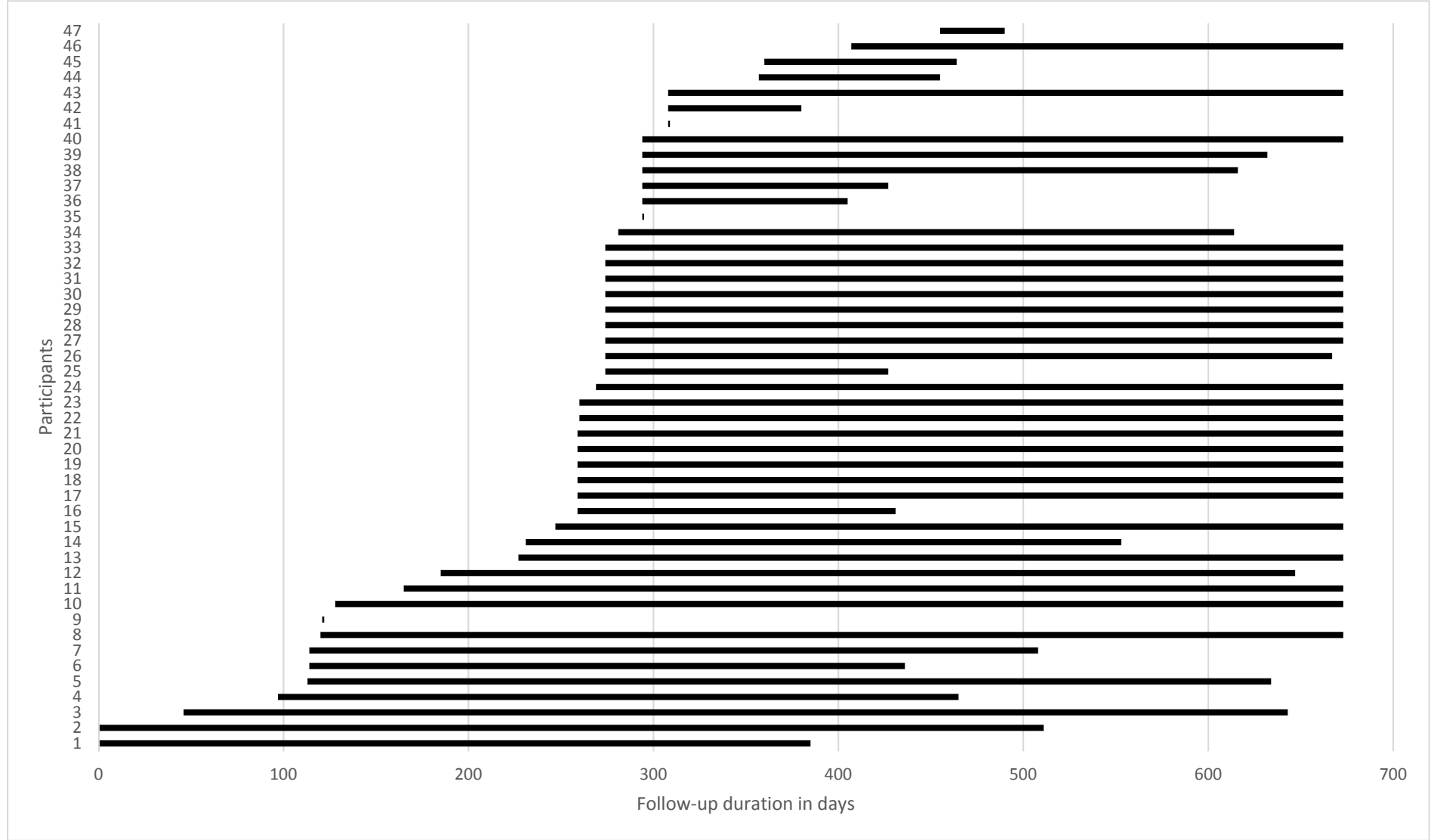613 *since start of study (different start days possible for patients)*
614

615 Figure 2:

616 *DAS28: Disease Activity Score 28; PROM: Patient-Reported Outcome Measure; RADAI-5: Rheumatoid Arthritis*
617 *Disease Activity Index-5; RAID: Rheumatoid Arthritis Impact of Disease.*
618 *Above: good congruence between PROM-values and DAS28-scores. Below: poor congruence between PROM-*
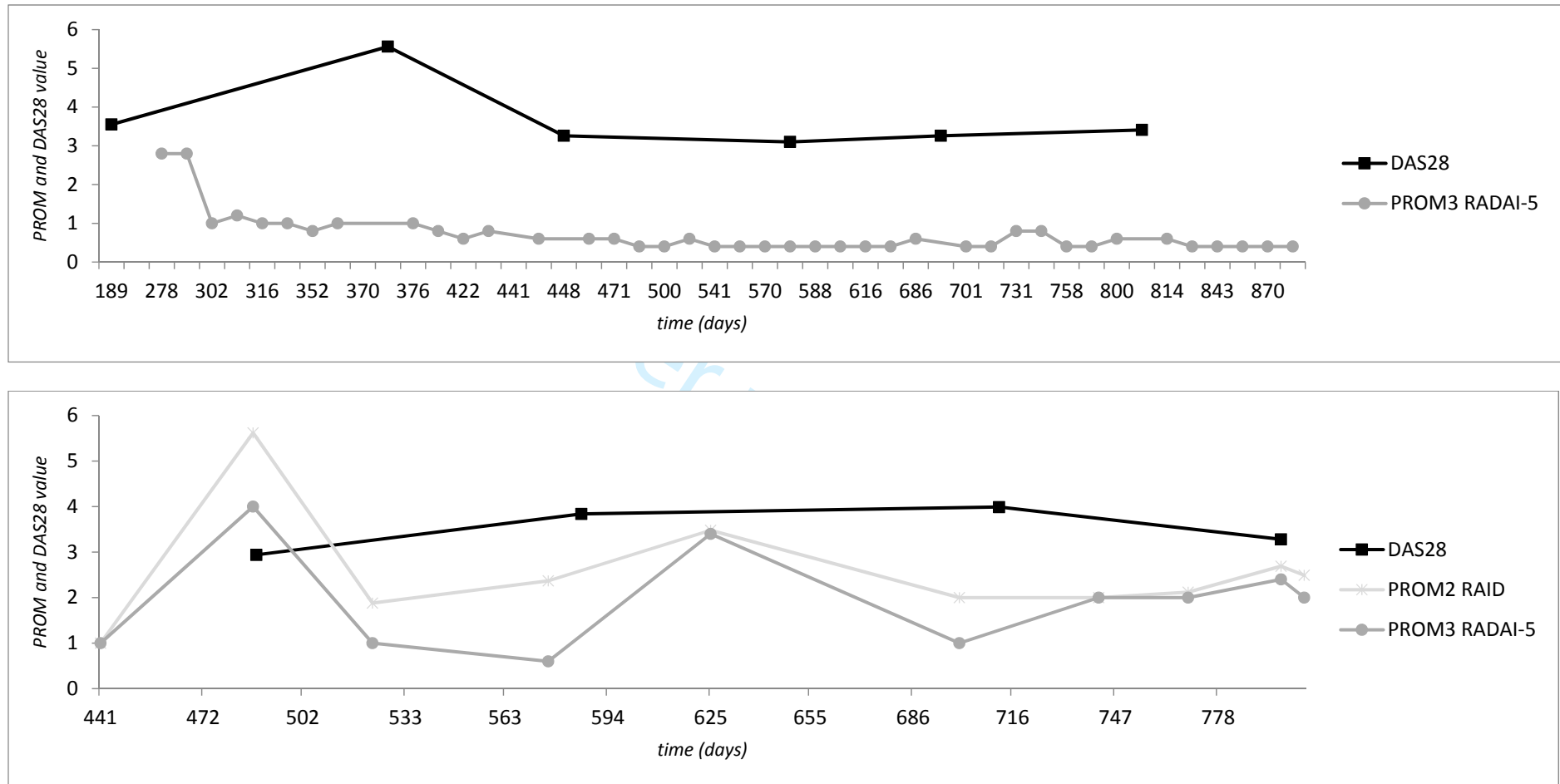619 *values and DAS28-scores*
620 *Poor: DAS28 course and PROM scores show opposite direction; Good: DAS28 course and the PROM scores show*
621 *the same direction*

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Figure 1. Follow-up duration in days of the 47 iMonitor participants

Y-axis: 47 patients who participated in the self-monitoring program, each line represents a patient; X-axis: days since start of study (different start days possible for patients)

Figure 2. Example of a positive (above) and negative (below) rating regarding the agreement between the PROMs and DAS28 course

DAS28: Disease Activity Score 28; PROM: Patient-Reported Outcome Measure; RADAI-5: Rheumatoid Arthritis Disease Activity Index-5; RAID: Rheumatoid Arthritis Impact of Disease.

Above: good congruence between PROM-values and DAS28-scores. Below: poor congruence between PROM-values and DAS28-scores

Poor: DAS28 course and PROM scores show opposite direction; Good: DAS28 course and the PROM scores show the same direction

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Appendix

Topic guide: "Patients' experiences regarding online self-monitoring of the disease course"

<u>Guideline related factors</u>

1. Which elements of the program are useful in your opinion, and why? Which are not useful, and why?

2. On what devices are you using the program?

3. What are your experiences with using iMonitor on these devices?

4. What do you think about the lay-out of iMonitor?

5. What do you think about the lay-out of de questionnaires/PROMs?

6. Do you encounter any technical problems while using iMonitor? If yes, which problems have occurred?

7. How did you experience creating a password?

<u>Patient related factors</u>

Motivation

8. For what specific reasons do you use the program?

9. What do you think are the benefits of using iMonitor?

10. Are there any reasons why you should not use the program?

Needs

11. To what specific needs does iMonitor comply?

Skills

12. Which skills are needed to use iMonitor properly according to you?

13. Do you have those skills?

Self-efficacy

14. Do you think you are capable to use iMonitor correctly? Why?

Adherence

You received an email-alert in case a PROM/PROMs could be completed.

15. What are your experiences with receiving those alerts?

16. What do you think about the idea of receiving alerts?

17. To what extent do these email-alerts activate you to complete the PROM/PROMs?

1

Social support

18. Are you supported by others (family, friends, peers) regarding the use of iMonitor?

    If yes: who and to what extent?

19. Do you talk with others about iMonitor? If yes, who?

20. How do you feel about receiving that social support?

Professional interaction

21. Do you/did you discuss the use of iMonitor with your rheumatologist or nurse specialist?

22. If yes, how do you/did you feel about that?

23. In case you attended the instruction class: What is your opinion about this instruction class?

Incentives and resources

Incentives/stimuli

24. In case you kept using the program: what made you keep using the program?

25. Which additional value do you experience by using iMonitor?

2

Knowledge

26. Do you gain more knowledge by using the program?

    a. If yes, how and to what extent?

    b. If no, why not?

Time investment

27. What do you think about the time investment needed in order to use iMonitor?

Capacity for organizational change

28. Do you think that using iMonitor could contribute to a reduction in the number of outpatient consultations, and why? Or why not?

29. Do you have any recommendations in order to recruit more patients?

Social, political and legal factors

30. How do you think about the privacy standards regarding the use of iMonitor?

31. Have there been any issues you needed to solve?

Any additional information you want to share with us? Any comments or suggestions?

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BMJ Open

Patients' experiences regarding self-monitoring of the disease course: an observational pilot study in patients with Inflammatory Rheumatic Diseases at a rheumatology outpatient clinic in the Netherlands

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2 Patients' experiences regarding self-monitoring of the disease course: an observational pilot study in

3 patients with Inflammatory Rheumatic Diseases at a rheumatology outpatient clinic in the

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37

Abstract

39   Objectives. Self-monitoring the disease course is a relatively new concept in the management of

40   patients with Inflammatory Rheumatic Diseases (IRDs). The aims of this pilot study were to obtain

41   patients' experiences with online self-monitoring, to assess information about the agreement between

42   the disease course assessed with Patient Reported Outcome Measures (PROMs) and an objectively

43   measured Disease Activity Score by the rheumatologist (DAS28), and to assess adherence to

44   predetermined PROM frequency intervals.

45

46   Design. Observational study using qualitative and quantitative methods.

47   Setting. The rheumatology outpatient clinic of a teaching hospital in the Netherlands (secondary care).

48   Participants: 47 Patients with an IRD who regularly attended the outpatient clinic.

49

50   Methods. Patients completed PROMs by using an online self-monitoring program. Their experiences

51   regarding self-monitoring were qualitatively assessed through a focus group discussion and telephone

52   interviews using a thematic analysis approach. Adherence to the predefined PROM frequency

53   (completed PROM assessments within the predetermined frequency) and the agreement between the

54   DAS28 course and PROM values (Rheumatoid Arthritis Disease Activity Index-5 (RADAI-5) and the

55   Rheumatoid Arthritis Impact of Disease (RAID)) were quantitatively assessed using descriptives.

56

57   Results. Forty-seven patients participated, most of them diagnosed with RA (n = 38, 80.9%). Three

58   themes were identified: knowledge about and insight into disease (activity), patient-professional

59   interaction, and functionality of the program. Mean adherence to the predetermined PROM frequency

60   was 68.1%. The RAID showed the best agreement with the DAS28 course. Mean participation time was

61   350 days.

2

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62

63 Conclusion. Patients were predominantly positive about online self-monitoring. They indicated that

64 they gained more knowledge about their disease, felt less dependent on the healthcare professional,

65 and valued the insight into their long-term disease course. Barriers were mostly related to technical

66 factors. Patients were able to and willing to self-monitor their disease, which could contribute to a

67 more efficient allocation of outpatient consultations in the future.

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70 **Article summary**

71

72 Strengths and limitations of this study:

73

74 • A strength of this study is the use of both qualitative and quantitative research methods,

75 providing a rich description of factors associated with self-monitoring

76 • Patients were closely involved during the development stage, execution, and evaluation

77 stage of this study, which increases the clinical relevance according to a user perspective

78 • Using validated Patient Reported Outcome Measures (PROMs) assessing disease activity and

79 disease impact allowed us to compare these PROM scores with objective, health professional

80 assessed scores

81 • The selective and small study population might have influenced the generalizability and

82 applicability of the study

83

4

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84   **Introduction**

85   In chronic care, there is a tendency toward personalized healthcare. Patients have become more

86   empowered and are increasingly involved in the planning and development of healthcare.[1-4] There is a

87   shift from a paternalistic model (in which the doctor is dominant and believes that patients need to be

88   guided through the decision making process) to a shared-decision making model (in which doctor and

89   patient make mutual, collaborative decisions). This shift requires an engaged patient who takes

90   responsibilities regarding day-to-day disease management.[5-8] As a result of this shift, new roles for

91   both patients and healthcare professionals (HCPs) have arisen. An example of what this new role

92   entails for a patient is self-monitoring, in which a patient undertakes self-measurement of vital signs,

93   symptoms, behavior, or psychological well-being through Patient-Reported Outcome Measures

94   (PROMs).[9 10] In some patients with Inflammatory Rheumatic Diseases (IRDs) such as Rheumatoid

95   Arthritis (RA), Psoriatic Arthritis (PsA), or Ankylosing Spondylitis (AS), self-monitoring may gradually

96   replace the traditional monitoring by HCPs.[11] Examples of disease-specific and validated PROMs in IRDs

97   that can be used in self-monitoring are the Rheumatoid Arthritis Impact of Disease[12 13] (RAID), which

98   measures disease impact, and the Rheumatoid Arthritis Disease Activity Index-5[14-16] (RADAI-5), which

99   measures disease activity. An example of a general or non-specific PROM is the Health Assessment

100   Questionnaire (HAQ), measuring functional status.

101   There are however also other reasons why self-monitoring in patients with IRD has gained

102   more interest. Usual care in patients with IRDs is primarily aimed at suppressing disease activity, in

103   order to prevent structural damage.[17 18] The disease activity can be measured using a composite index,

104   the Disease Activity Score using 28 joint counts[19], which measures tender and swollen joint counts,

105   acute phase response, and a patient's general health assessment. The Treat-to-Target Task Force

106   recommends rheumatologists to monthly assess patients with moderate or high disease activity, and

107   patients with controlled and low disease activity every three to six months.[20] In practice, however,

108   these frequencies are not always met for various reasons. This strategy causes time constraints and a

109   growing workload among rheumatologists, making it not manageable for all rheumatologists to comply

5

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110   fully to the frequent assessments.[21] Another reason is connected to the aging population. The number

111   and proportion of patients with IRDs aged 65 and over will increase in the near future.[22] Self-

112   monitoring of the disease course using disease-specific PROMs such as RAID or RADAI-5 could prove

113   to be a solution in diminishing the number of consultations.[23] As disease activity can only be objectively

114   assessed during outpatient consultations, it remains unclear what happens to the disease activity in-

115   between consultations. Fluctuations and peeks in disease activity are easily missed or they remain

116   unnoticed, which could have disastrous consequences regarding joint damage.[17] Self-monitoring might

117   also give a better insight into these fluctuations of disease activity in-between outpatient clinical

118   consultations. Moreover, some patients visit their rheumatologist while their disease activity is under

119   control, thereby contributing to unnecessary outpatient consultations. Summarizing, self-monitoring

120   of disease activity in IRDs as a first step toward personalized healthcare enables patients as well as

121   HCPs to get insight into the disease activity course over time. Moreover, it may lead to a more

122   consistent reporting in the long term and may contribute to optimizing the number, timing, and

123   efficiency of consultations.[11 23] By completing PROMs, patients who need further medical attention can

124   be identified and receive additional medical attention. Moreover, completion of a PROM will help a

125   patient to prepare for a visit and it could improve the communication between physician and patient.[24]

126   [25]

127   In the present study an online self-monitoring program was pilot-tested in order to test the

128   feasibility of self-monitoring before implementation of a self-monitoring program in daily clinical

129   practice. The aims of this study were to obtain patients' experiences regarding online self-monitoring,

130   to assess the agreement between the disease course assessed with disease-specific PROMs (RAID and

131   RADAI-5) and an objectively measured disease activity score (DAS28) by the rheumatologist, and to

132   assess the adherence to predetermined PROM frequency intervals.

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6

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134   **Methods**

135   *Study design*

136   This observational pilot study using quantitative and qualitative research methods, was conducted at

137   a teaching hospital in Uden (the Netherlands) at the rheumatology outpatient clinic from 6 July 2015

138   until 9 May 2017.

139

140   *Inclusion criteria*

141   In order to be eligible for this study, patients had to be diagnosed with an IRD according to the

142   ACR/EULAR criteria.[26] Furthermore, they needed to have an electronic device (laptop/PC, tablet or

143   Smartphone) with access to the Internet, and they needed to be able to sufficiently read and write

144   Dutch. Patient inclusion started in July 2015 and we included the last patient in October 2016.

145

146   *Follow-up duration*

147   Patients were able to withdraw from the program at any time point. We defined early study

148   termination in two manners: when a patient reported to withdraw from the self-monitoring program,

149   this was evaluated as the end date. Some patients did not report dropping out of the study but did

150   stop completing PROM(s). End of study in these cases was set by adding the interval time to the date

151   the last PROM was filled in. For example, a patient with a four-week PROM frequency (28 days)

152   completed the last PROM on 1 March 2017. For this patient, end of study date was set on 29 March

153   2017.

154

155   *Self-monitoring program*

156   iMonitor, the online self-monitoring program tested in this study, was developed by Pfizer.[27] The

157   program was accessible through a laptop, tablet or Smartphone by filling in a user name, password,

158   and pin code. The program complied with the required privacy standards. Because the program was

159   intended to stimulate patient involvement, personalized healthcare and patient self-management,

7

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160 patients selected their preferred PROM(s) and PROM frequency (one-, two-, four-, six- or eight-weekly)

161 in advance and the system generated an email-alert for filling in a PROM (or PROMs) accordingly.

162 Patients were able to complete one or more PROMs within a timeframe of 24 hours. They could send

163 a message to the HCPs in case of questions or notifications by using the message option. In case of

164 urgent matters, they could contact the outpatient clinic by telephone.

165

166 *Patient-Reported Outcome Measures (PROMs)*

167 Available disease-specific PROMs for patients with RA were the RAID and the RADAI-5, measuring

168 disease impact (0-10; 10 = severe impact of disease activity) and disease activity (0-10; 10 = severe

169 disease activity). Patients with AS could fill in the disease-specific Bath Ankylosing Spondylitis Disease

170 Activity Index (BASDAI), measuring disease activity (0-10; 10 = severe disease activity), and/or the Bath

171 Ankylosing Spondylitis Functional Index (BASFI), measuring physical function (0-10; 10 = severe

172 functional limitation). The HAQ, general PROM that measures physical function, was available for all

173 patients (0-3; 3 = severe disability). Patients could opt to assess one to three PROMs. Completion of all

174 PROMs took about 5 minutes. After completion, the PROM scores were subsequently displayed in a

175 graph. Additionally, DAS28 scores (0-10; remission: DAS28 <2.6, low disease activity: ≥ 2.6 DAS28 < 3.2,

176 moderate disease activity: ≥ 3.2 DAS28 ≤5.1, high disease activity: DAS28 > 5.1) could be added to the

177 graph by the HCP. These DAS28 scores were obtained by the HCPs during outpatient consultations and

178 were kept in the electronic medical files from the hospital.

179

180 *Procedure - Recruitment*

181 Patients were informed about this pilot study and recruited in several ways. Firstly, we used purposive

182 sampling: rheumatologists themselves asked possible suitable patients to participate during

183 outpatient consultations during the entire study period. Secondly, during general information

184 meetings at the hospital, patients were informed about the study and were able to sign up. Lastly,

185 leaflets about the study were available in the waiting room and patients were informed about the

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186 study through the hospital's website. Patients received a manual containing information regarding

187 access to and use of the program. However, a substantial number needed additional training, which

188 was provided by instruction classes. After patients had been instructed how to use the program, they

189 could indicate which PROM(s) they preferred to fill in by showing them the paper versions. Moreover,

190 they were asked to indicate their desired frequency option. Patients who agreed to take part in the

191 study were asked to sign a consent form. During the regular outpatient consultations, rheumatologists

192 were expected to provide feedback to the patient about the patient's disease course and PROM

193 results.

194

195 *Data collection and analysis*

196 Quantitative methods

197 ▪ Adherence and agreement

198 Firstly, we determined adherence to the predetermined PROM frequency by assessing whether a

199 patient had completed (yes or no) the PROM(s) in the predetermined time interval. Adherence was

200 calculated as the number of completed assessments by the patient divided by the number of PROM

201 assessments that should have been completed according to the chosen interval of the patient times

202 100%. For example, a patient with a weekly PROM frequency participated for one year. This patient

203 should have received 52 email-alerts, so 52 PROM assessments should have been completed. This

204 patient completed 40 PROM assessments, so adherence is (40/52*100 =) 76.9%. Secondly, we

205 determined the agreement between the DAS28 course and PROM values. Two researchers (LR and

206 PvR) independently assessed agreement by comparing the DAS28 course with the corresponding

207 PROM-value(s) from the RAID and/or RADAI-5 using two categories (poor and good) and discussed

208 discrepancies. The RAID and the RADAI-5 were used, because these two disease-specific PROMs

209 measure disease impact and activity, whereas the HAQ is non-disease specific. 'Good' was used in

210 cases where the DAS28 course and the PROM scores showed the same direction (i.e. the DAS28 course

211 increased and PROM scores as well). 'Poor' was used in cases where the DAS28 course and PROM

9

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212   scores showed opposite directions (the DAS28 course increased and PROM scores decreased (or the

213   other way around). Data from patients with at least three PROM values (falling within a fourteen-day-

214   window with DAS28 assessment) were assessed.

215

216   Qualitative methods

217   Patients' experiences with the self-monitoring program were obtained via a focus group and semi-

218   structured interviews. The purpose of the focus group and interviews was to gain insight into relevant

219   factors that might hinder or facilitate patients using the self-monitoring program. The checklist from

220   Flottorp et al.[28] served as an inspiration for a semi-structured topic guide (see appendix). Relevant

221   domains for our topic guide were: program factors; patient factors; professional-patient interaction

222   factors; and resources. Prior to the start of the focus group discussion we conducted a telephone

223   interview with one patient to check the appropriateness of the topic guide and to check whether the

224   questions were clear. During the focus group discussion, an experienced moderator (PvR) guided the

225   discussion. Patients unable to attend the focus group were interviewed by telephone, using the same

226   topic guide. All participating patients had at least six months experience with the self-monitoring

227   program.

228

229   *Qualitative analysis*

230   The interviews and focus group discussion were recorded. The recordings were transcribed ad verbum

231   by an independent agency. One of the researchers (LR) and a research assistant independently coded

232   the transcripts, in order to enhance the coding process, data interpretability, and trustworthiness.

233   They used the method 'thematic analysis' in which the codes were derived from the data with the

234   purpose to describe relevant factors regarding self-monitoring and to identify categories and themes.

235   A constant comparative method was used for the analysis of the emerging themes. Any discrepancies

236   in the analysis were discussed until consensus was reached[29]. Afterwards, two researchers (LR and AH)

237   agreed on a provisional categorization and overarching themes. These categories and overarching

10

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238   themes were also discussed with a third and fourth researcher (SR and PvR). The COnsolidated criteria

239   for REporting Qualitative research (COREQ) checklist[30] was mainly used as guidance for the reporting

240   of our qualitative research. We conducted coding and analysis by using a qualitative software program

241   (Atlas.ti).

242

243   *Patient and public involvement*

244   Firstly, patient involvement was needed during the establishment of the topic guide, which was pre-

245   tested among one patient in order to check if the questions were comprehensible and clear. Secondly,

246   patients were encouraged to give suggestions and comments regarding the use of the program during

247   the entire study period. This feedback was used as input for the implementation of a revised version

248   of the program at a later stage. Lastly, the study participants exchanged their experiences with the

249   self-monitoring program with other patients (users and non-users) during research meetings at the

250   hospital.

251

252   **Results**

253   *Study population*

254   In this pilot study, slightly more women than men participated (n=27; 57.4%). Mean($\pm$) age was

255   57.3(10.7) years. Most patients (n=38) were diagnosed with RA (80.9%), while nine patients were

256   diagnosed with a SpA (eight patients with PsA, and one patient with AS). Other baseline characteristics

257   are given in Table 1. Of over 1800 patients with an IRD, we included 47 patients during the study period.

258   Two patients eventually signed the informed consent form but did not complete any PROMs and were

259   withdrawn from the study. An overview of the follow-up duration is presented in Figure 1. In total,

260   twenty-three patients participated from the start (different start dates were possible) until the end of

261   the study (48.9%). The follow-up duration of the 45 patients who completed PROMs varied between

262   14 and 597 days, with a mean of 350 days.

263

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264   < Figure 1. Follow-up duration in days of the 47 iMonitor participants >

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265   Table 1. Baseline characteristics of the 47 patients using the self-monitoring program

266

Characteristics	Rheumatoid arthritis, n = 38	SpA group, n = 9
Patient and disease characteristics		
Age, years, mean (SD)	57.74 (11.17)	55.67 (8.69)
Female, n (%)	20 (52.6%)	7 (77.8%)
Disease duration, years, mean (SD)	8.08 (4.74)	9.89 (7.25)
DAS28-score, mean (SD)	3.19 (1.25)	n.a.
Educational level		
Low, n (%)	12 (34.3)	3 (37.5)
Middle, n (%)	11 (31.4)	3 (37.5)
High, n (%)	12 (34.3)	2 (25.0)
Baseline PROM-values		
HAQ [0.00-3.00] (n=27), mean, SD, range	0.78 (0.61) [0.00;2.38]	0.98 (0.60) [0.13;1.88]
RADAI-5 [0.00 – 10.00] (n=24), mean, SD, range	3.49 (2.32) [0.00;7.40]	n.a.
RAID [0.00 – 10.00) (n=35) mean, SD, range	3.47 (2.28) [0.00;7.61]	n.a

13

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BASFI [0.00 – 10.00] (n=1), mean, SD	n.a.	5.05
BASDAI [0.00 – 10.00] (n=1), mean, SD	n.a.	4.60
Medication use		
csDMARD, n (%)	36 (94.7%)	8 (88.9%)
bDMARD, n (%)	12 (32.0%)	3 (33.3%)

267 *SpA: Spondylarthropathy; HAQ: Health Assessment Questionnaire (3 = severe disability); RADAI-5: Rheumatoid Arthritis Disease Activity Index-5 (10 = severe disease activity);*
268 *RAID: Rheumatoid Arthritis Impact of Disease (10 = severe impact of disease activity); BASFI: Bath Ankylosing Spondylitis Functional Index (10 = severe functional limitation);*
269 *BASDAI: Bath Ankylosing Spondylitis Disease Activity Index (10 = severe disease activity); csDMARD: conventional synthetic Disease-Modifying Antirheumatic Drug; bDMARD:*
270 *biological Disease-Modifying Antirheumatic Drug*

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271   *Quantitative*

272   ▪   Adherence and agreement

273   Twenty-seven patients (57.4%) were able to use the self-monitoring program without additional

274   training, whereas twenty patients (42.6%) attended the instruction classes. With regard to the PROM

275   preferences, RAID was chosen most often, namely 34 times. HAQ and RADAI-5 were chosen 27 and 23

276   times, respectively. Seventeen patients chose to complete one PROM, 21 patients chose to complete

277   two PROMs, and nine patients chose to complete three PROMs. Mean adherence to the

278   predetermined PROM frequency was 68.1%, see table 2. With regard to the agreement between the

279   DAS28 course and PROM values, RAID scored best (from 25 assessments, 17 times a score of 'good',

280   68.0%). RADAI-5, on the other hand, scored 'good' in ten out of seventeen assessments (58.8%), see

281   table 3. Figure 2 shows two examples of assessments regarding the agreement between the DAS28

282   course and PROM values.

283

284   Table 2. Data regarding PROM frequency, PROM scores, and adherences rates, n = 47

Item	n (%)
PROM frequency	
1 week	4 (8.5)
2 weeks	10 (21.3)
4 weeks	31 (66.0)
≥ 6 weeks	2 (4.3)
Number of PROMs to complete, chosen by patient	
One	17 (36.17)
Two	21(44.68)
Three	9 (19.15)
Mean adherence (%) to the predetermined PROM frequency	68.1%

285   *PROM: Patient-Reported Outcome Measure; Adherence to the predefined PROM frequency: calculated by*

286   *dividing the number of completed PROMs by the number of PROM assessments (based on the reminder emails)*

287   *that should have been completed according to the chosen PROM frequency by the patient, times 100*

288

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289   < Figure 2. Example of a positive (above) and negative (below) rating regarding the agreement between

290   the PROMs and DAS28 course >

291   Table 3. Agreement (poor or good) between the DAS28 course and disease-specific PROMs (RAID and

292   RADAI-5), assessed in n = 33 patients

PROM	Poor	Good	Total
RAID	8 (32.0%)	17 (68.0%)	25
RADAI-5	7 (41.2%)	10 (58.8%)	17

293   *PROM: Patient-Reported Outcome Measure; RAID: Rheumatoid Arthritis Impact of Disease; RADAI-5:*

294   *Rheumatoid Arthritis Disease Activity Index-5; DAS28 course: Disease Activity Score using 28 joint counts,*

295   *assessed by rheumatologists; Good: DAS28 course and the PROM scores showed the same direction. Poor:*

296   *DAS28 course and PROM scores showed opposite direction*

297

298   *Qualitative*

299   We conducted the focus group discussion and telephone interviews between December 2016 and June

300   2017. The interviews lasted between 24 and 42 minutes, while the focus group discussion lasted one

301   hour and 22 minutes. Six patients attended the focus group discussion, and four patients participated

302   in a telephone interview (five female and five male patients).

303

304   *Patients' experiences regarding the self-monitoring program*

305   Three main themes emerged from the focus group discussion and interviews: knowledge about and

306   insight into disease (activity), patient-professional interaction, and functionality of the program. Five

307   subcategories emerged: Disease (self)management, discussing results with healthcare professionals,

308   technical factors, user interface and PROMs, and patients' suggestions for improvement. Table 4

309   provides an overview of the themes and subcategories regarding the qualitative analysis.

310

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312   Table 4. Themes and subcategories with regard to the qualitative analysis of patients' experiences

313   with iMonitor

Theme	Subcategory
Knowledge about and insight into disease (activity)	n.a.
Patient-professional interactions	- Disease (self)management
	- Discussing results with healthcare professionals
Functionality of the program	- Technical factors
	- User interface and PROMs
	- Patients' suggestions for improvement

314   *Three main themes and five subcategories emerged from the qualitative analysis. The checklist from Flottorp et*

315   *al.[28] served as a guide for the establishment of the topic guide*

316

317   *Theme I: Knowledge about and insight into disease (activity)*

318   The most cited reason for using the self-monitoring program was that patients gained insight into their

319   (long-term) disease activity course. Most patients indicated that using the program led to more

320   knowledge and awareness about their disease. Some patients reported that they recognized peaks in

321   disease activity earlier and could subsequently prepare for an exacerbation. Patients also mentioned

322   that they became more prudent when noticing a flare. When asked more specifically about patients'

323   experiences with the agreement between their PROM values and DAS28 scores, most patients thought

324   their PROM values were in line with their DAS28. One patient noted: "*By consciously using the*

325   *program, it was easier to find things about rheumatism and to gain more insight into the question*

326   *'What is rheumatism?'*"

18

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327 *Theme II: Patient-professional interactions*

328 ▪ Disease (self)management

329 By using the self-monitoring program, most patients felt less dependent on their HCP. Patients

330 appreciated the fact that they were able to influence their own disease management. Overall, patients

331 thought that the self-monitoring program could contribute to a reduction in the number of outpatient

332 consultations.

333

334 A patient told: *"I can monitor my disease course, keep record of my disease activity in-between*

335 *consultations, without being dependent on the professional"*

336

337 ▪ Discussing results with healthcare professionals

338 Patients emphasized the importance of discussing the results of online monitoring (e.g. PROM values)

339 with their HCP (rheumatologist or nurse). Most of all, they wanted to know if they were 'doing it right'.

340 Some patients expressed the value of discussing their results with their HCP. One patient provided the

341 following scenario: *"I used to look at the back of a computer screen during an outpatient visit. Now,*

342 *I'm looking at the computer screen together with my HCP, sharing and discussing the PROM values and*

343 *our ideas about my treatment"*. Patients who did not discuss their values felt the need to do so in the

344 future.

345

346 *Theme III: Functionality of the program*

347 ▪ Technical factors

348 Barriers regarding the use of the self-monitoring program were mostly related to technical aspects.

349 Some patients had problems with the login system, which hindered them from accessing the website.

350 Regarding the PROM reminder emails: the system generated an email alert at fixed time points (e.g.

351 four-weekly). Some patients noticed that the system generated an alert at unfortunate time points or

352 even no alert at all.

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353 ▪ User interface and PROMs

354 Twenty-seven patients joined the instruction classes, which were perceived to be very helpful. Overall,

355 patients were satisfied with the user interface of the program. They reviewed the layout as clear and

356 comprehensible. Some patients experienced difficulties with the content and layout of the PROMs. For

357 example, some patients thought the questions were not specific enough. Furthermore, the program

358 did not use a progress bar and there was no 'Accomplish' sign after completing a PROM. As a result –

359 in case of completing more than one PROM – some patients did not know how many PROMs they had

360 actually completed.

361

362 ▪ Patients' suggestions for improvement

363 Most commonly mentioned suggestions concerned adjustments to clarify PROM values, for example

364 a textbox to type a comment in case of an exacerbation. Additionally, patients provided suggestions

365 concerning the possibility of also having access to their lab values in the self-monitoring program, as

366 well as the possibility of having a more detailed look at a certain time period.

367

368

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369 **Discussion**

370 This study collected experiences from patients with IRDs regarding online self-monitoring. Moreover,

371 we assessed adherence to the predefined PROM frequency to measure disease activity and the

372 agreement between the PROMs and the DAS28 course. The qualitative analysis revealed three themes:

373 knowledge about and insight into disease (activity), patient-professional interaction, and functionality

374 of the program. Overall, patients were mainly positive about the program and were willing to continue.

375 Most of them participated for an extended period: mean follow-up duration was almost one year.

376 Mean adherence to the predefined PROM frequency was 68.1%, and the disease-specific and patient-

377 reported RAID showed best agreement with the DAS28 assessed by the rheumatologist. Patients

378 reported that they gained more knowledge about their disease and felt less dependent on their HCP.

379

380 By self-monitoring disease activity, patients obtained a graphic overview of their PROM values over

381 time, which gave them insight into their disease course. Patients reported that they appreciated both

382 this long-term insight into their disease pattern, and the ability to anticipate on an exacerbation. They

383 also indicated that they gained more knowledge about their disease, they felt better prepared for a

384 consultation, and felt less dependent on their HCP in handling their disease. Literature about self-

385 monitoring in diabetes already showed that knowledge about the disease and self-monitoring are

386 related[10]. Although some knowledge is a prerequisite for self-monitoring, the process of self-

387 monitoring contributes to the further expansion of disease-related knowledge. Adequate disease-

388 related knowledge is important, since it may influence patients' decisions regarding treatment,

389 compliance, and self-management performance,[31] as well as the ability to recognize signs, symptoms,

390 and patterns,[10] which is supported by a study about experiences with telehealth in patients with RA.[32]

391 All of these aspects are essential in shared-decision making,[33] while also being beneficial to the

392 efficiency of consultations. From the perspective of the HCP, it is important to give feedback to the

393 patients about the results of self-monitoring during outpatient consultations, a fact that was

394 emphasized by our study participants during the interviews. Those who had not received feedback

21

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395   about their PROM-values and/or disease activity course were less motivated to continue with the

396   program. The importance of feedback was emphasized in a study in which patients with early

397   rheumatoid arthritis received visual feedback by their HCP about their disease progression. Compared

398   to patients who received standard care, patients who received feedback showed significant differences

399   regarding disease activity parameters.[34] Obtaining insight into the long-term disease activity course,

400   and being able to anticipate on an exacerbation, might benefit the effectiveness of the delivered care

401   as well. Patients will be able to respond to a deterioration in a timely manner and will have a greater

402   chance to receive the care they need at the right time, resulting in a decrease of the cumulative disease

403   activity. On the other hand, fewer consultations are possible if the disease activity is stable, which will

404   eventually lead to less frequent outpatient visits. That reduction of health care costs can be obtained

405   by introducing patient-report outcomes (PROs) in the follow-up was shown by a study on tele-health

406   in RA. Patients received PRO-based health follow-up and were scheduled for telephone consultations

407   by a rheumatologist or nurse. Similar results regarding disease control were found for the telehealth

408   group compared with conventional follow-up.[35] Studies on self-monitoring in other chronic diseases

409   have already proven its effectiveness, such as better control of blood glucose levels in diabetes,[36 37]

410   reduction in mortality rates in heart failure,[38 39] reductions in blood pressure in hypertension,[40 41] and

411   reductions in thromboembolic events in patients using anticoagulation therapy.[42] The effectiveness of

412   self-monitoring resulted in a reduction in hospital readmissions in patients with hypertension, COPD

413   and heart failure.[43] Patients in our study believed that self-monitoring could lead to a reduction in

414   consultations, although they stressed the need and possibility for contacting the outpatient clinic when

415   necessary. To our knowledge, there are no studies in IRDs on the efficiency of online remote self-

416   monitoring of the disease activity by completing PROMs using an online program on reduction in

417   consultations. Further research will therefore be needed.

418

419   Barriers regarding online self-monitoring were mostly related to the functionality of the online

420   monitoring system. Some patients experienced log-on problems, while others would like to have

22

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421 access in the system to more extensive information about their health status in general (e.g. blood test

422 results). Despite these barriers, almost half of the participants reached the end of the study, and the

423 follow-up duration was almost one year. Literature in the field of technology and innovations indicates

424 that factors such as compatibility, complexity, and relative advantage influence the adoption of new

425 innovations.[44] Therefore, a self-monitoring program should be comprehensible and user-friendly and

426 preferably integrated into an existing hospital system. In addition, we recommend screening patients

427 on motivation and computer skills and providing guided practice. We also recommend to let patients

428 choose their own preferred interval and PROM(s). Forcing patients to complete PROMs at predefined

429 intervals set by researchers does not support our idea of self-management and might impede patients'

430 motivation. Some patients opted for weekly self-assessments, which might seems to be too frequent

431 for us as healthcare professionals. However, especially in an early or active phase of the disease, this

432 seems to provide some measure of support for some patients. Patients were willing and able to self-

433 monitor their disease. The mean adherence to the predetermined PROM frequency was reasonably

434 high: 68.1%. This could be partly explained by system-related factors such as the reminders, which

435 were considered very useful in encouraging patients to complete the questionnaire. Next to this,

436 patient-related factors such as intrinsic motivation might also have influenced this percentage. Since

437 there was no real 'need' or urgency for self-monitoring in our study, as opposed to blood glucose

438 monitoring in diabetes, for example, reaching complete (100%) adherence was not a realistic option.

439 Both the RAID and RADAI-5 had acceptable agreements with the DAS28, 68.0% and 58.8% respectively.

440 Due to the relatively small number of patients no conclusion can be drawn which PROM should be

441 used to self-monitor the disease course.

442

443 By using qualitative methods we were able to examine the experiences and barriers that influence

444 participation in self-monitoring programs. This resulted in a thorough description of factors related to

445 self-monitoring, and guidance for further development of appropriate tools. The main limitation of this

446 study was the selective, highly motivated study population due to the purpose sampling. Because of

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447   the small study sample, it remains unclear which percentage of the total population will be eligible for

448   self-monitoring. However, the main purpose was to gather experiences about self-monitoring, which

449   were provided by the extensive comments of the patients. With regard to difficulties in data

450   interpretation in qualitative research, it remains unclear whether we actually truly grasped what

451   patients were really thinking or feeling. Interpretations might have been influenced by the professional

452   backgrounds and theoretical perspectives of the researchers. However, the coding process was done

453   together with a collaborator who did not have a scientific background. Another limitation is connected

454   to the fact that the moderator was the main care provider for some patients which might have

455   influenced their responses. Despite these limitations, we extensively and thoroughly discussed our

456   data several times in order to identify the relevant categories and emerging themes regarding self-

457   monitoring.

458

459   By monitoring their disease activity at home, patients were involved in their own disease management

460   and had individual control and responsibilities. During outpatient visits, patients might be better

461   prepared to interact with their HCP, which will improve shared-decision making, contributing to the

462   concept of personalized care. Self-monitoring – as a prerequisite of self-management – might benefit

463   the cost-effectiveness of outpatient consultations. Efficiency gains are reflected in a reduction in the

464   number of consultations without any increase in costs. At the same time, patient outcomes and

465   patients' satisfaction should either remain stable or increase. This study is a first step toward

466   personalized healthcare and involving the patient in decision making about their disease treatment.

467   Findings from our study were used to implement a self-monitoring program at our outpatient clinic

468   using the Integrated Electronic Patient Record from the hospital.

469   The present study showed the potential of self-monitoring as a first step toward disease self-

470   management. Patients reported that they gained more knowledge, felt less dependent on their HCP,

471   and most of them were able to monitor their disease. Therefore, we believe that self-monitoring can

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472 benefit the quality and efficiency of healthcare. Further research will be needed to confirm the cost-

473 effectiveness of self-monitoring.

474

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477 would also like to thank Pfizer for getting the opportunity to test iMonitor.

478

479 **Contributors**

480 Study acquisition: PvR. Conception and design: all authors. Obtaining ethical approval: LR.

481 Qualitative data collection: LR pretested the topic guide. Focus group discussion: PvR functioned as

482 moderator and LR as observer. Telephone interviews were conducted by LR. Quantitative data

483 collection: PvR and SR (mainly clinical data), whereas LR obtained data derived from the self-

484 monitoring program. Qualitative data analysis: LR was involved as one of the coders during the coding

485 process, together with a research assistant. Provisional categorization of themes: LR and AH. Final

486 version of the categorization of themes and categories: all authors. Quantitative data analysis: all

487 authors. Writing: LR drafted the first version of the manuscript. PvR, AH and SR revised the manuscript.

488 The final manuscript has been seen and approved by all authors.

489

490 **Conflicts of interest**

491 This study was partly funded by Pfizer (pharmaceutical company). Pfizer was able to access data

492 available from iMonitor. Pfizer was not involved in any medical policy related to the study participants.

493

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496

497 **Ethics**

25

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498   The present study fulfills the Helsinki criteria and was approved by the Medical Ethical Committee of

499   the Radboud University Medical Center Nijmegen approved the study (2016-2435) and concluded that

500   no specific obligations were applicable to this research.

501

502   **Data**

503   (Anonymous) data are available upon reasonable request by contacting the corresponding author by

504   email.

505

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612 **Figure legends**

613 Figure 1:

614 *Y-axis: 47 patients who participated in the self-monitoring program, each line represents a patient; X-axis: days*
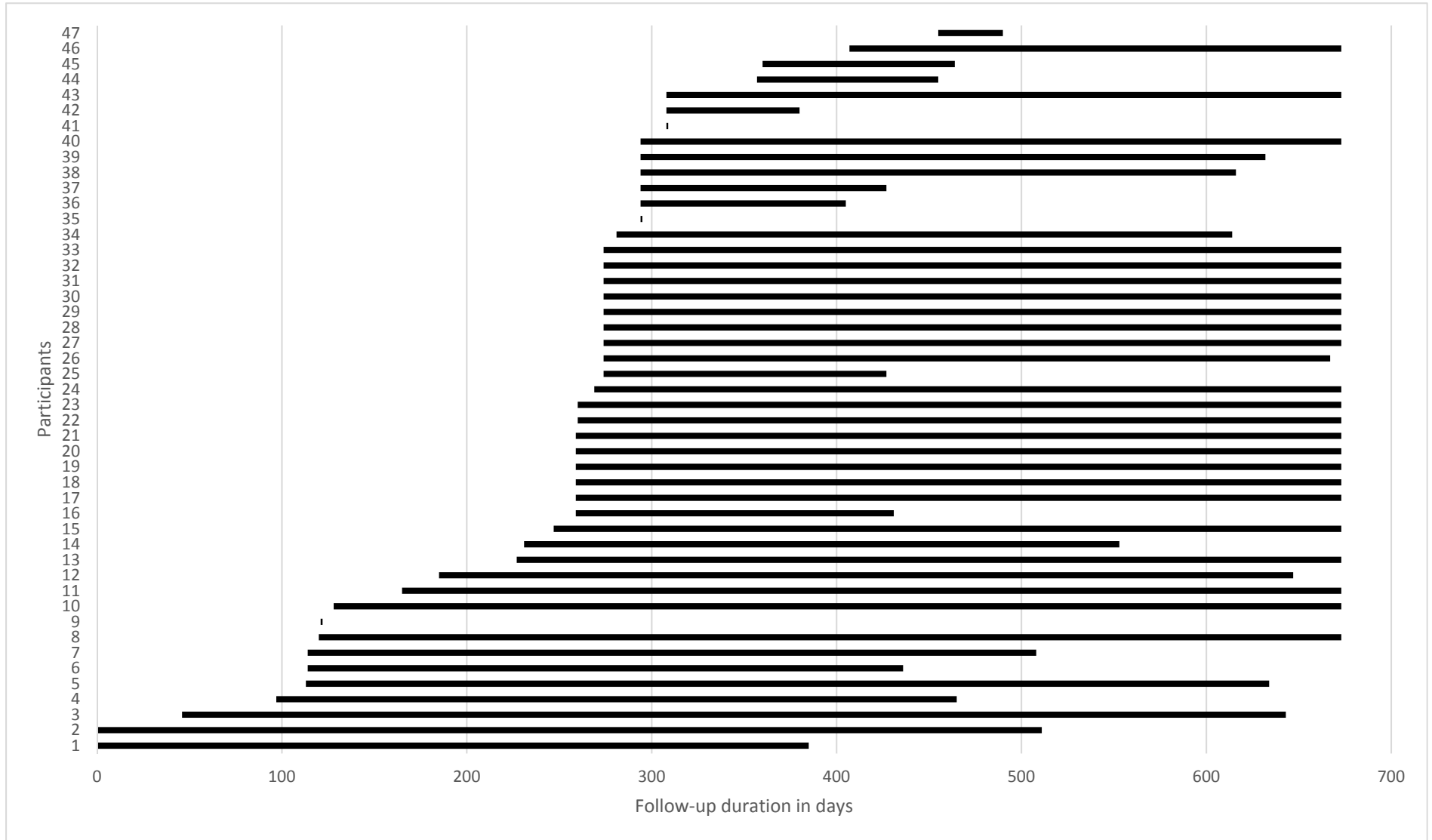615 *since start of study (different start days possible for patients)*
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617 Figure 2:

618 *DAS28: Disease Activity Score 28; PROM: Patient-Reported Outcome Measure; RADAI-5: Rheumatoid Arthritis*
619 *Disease Activity Index-5; RAID: Rheumatoid Arthritis Impact of Disease.*
620 *Above: good congruence between PROM-values and DAS28-scores. Below: poor congruence between PROM-*
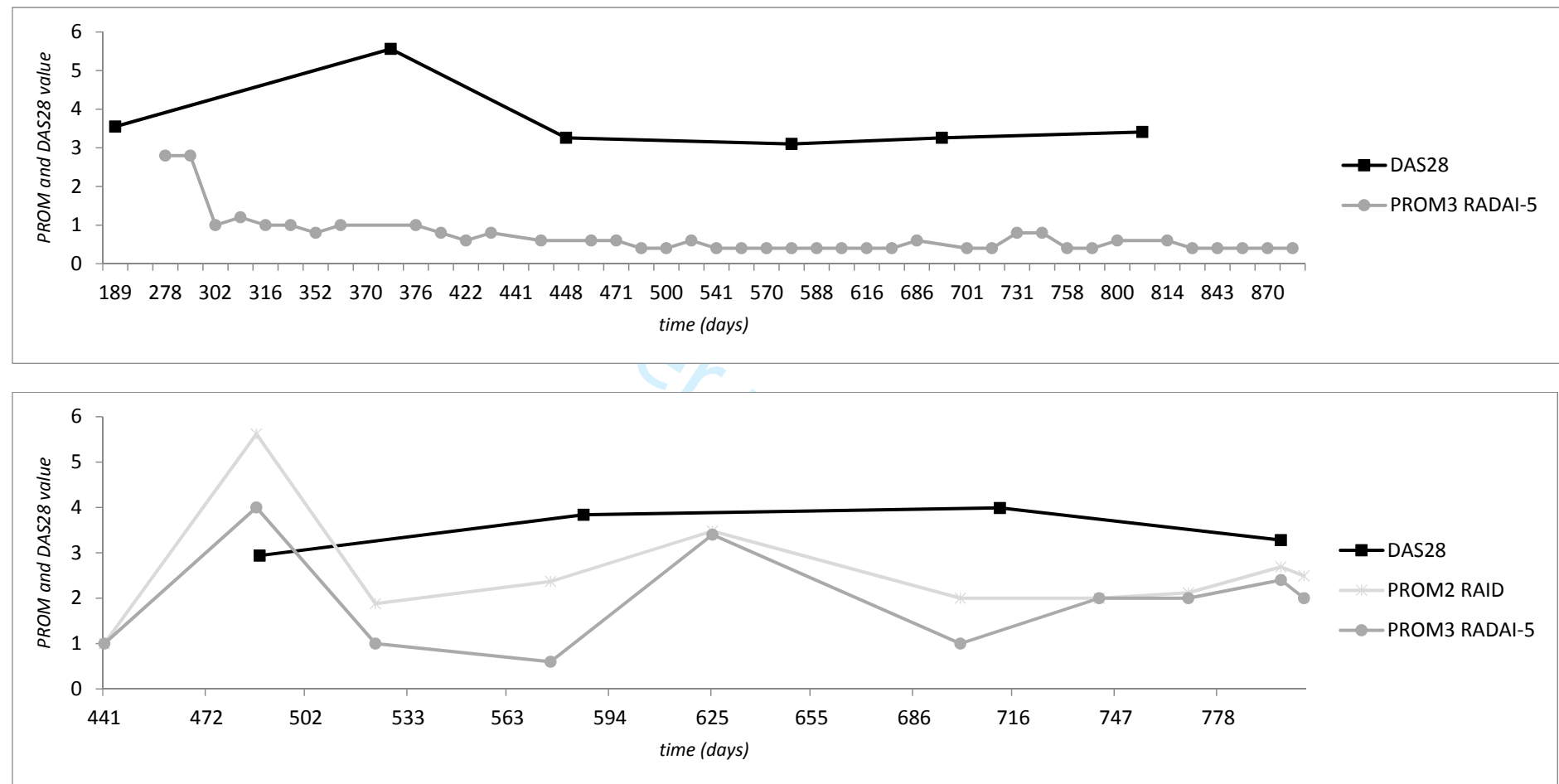621 *values and DAS28-scores*
622 *Poor: DAS28 course and PROM scores show opposite direction; Good: DAS28 course and the PROM scores show*
623 *the same direction*

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Figure 1. Follow-up duration in days of the 47 iMonitor participants

Y-axis: 47 patients who participated in the self-monitoring program, each line represents a patient; X-axis: days since start of study (different start days possible for patients)

Figure 2. Example of a positive (above) and negative (below) rating regarding the agreement between the PROMs and DAS28 course

DAS28: Disease Activity Score 28; PROM: Patient-Reported Outcome Measure; RADAI-5: Rheumatoid Arthritis Disease Activity Index-5; RAID: Rheumatoid Arthritis Impact of Disease.

Above: good congruence between PROM-values and DAS28-scores. Below: poor congruence between PROM-values and DAS28-scores

Poor: DAS28 course and PROM scores show opposite direction; Good: DAS28 course and the PROM scores show the same direction

Appendix

Topic guide: "Patients' experiences regarding online self-monitoring of the disease course"

Guideline related factors

1. Which elements of the program are useful in your opinion, and why? Which are not useful, and why?

2. On what devices are you using the program?

3. What are your experiences with using iMonitor on these devices?

4. What do you think about the lay-out of iMonitor?

5. What do you think about the lay-out of de questionnaires/PROMs?

6. Do you encounter any technical problems while using iMonitor? If yes, which problems have occurred?

7. How did you experience creating a password?

Patient related factors

Motivation

8. For what specific reasons do you use the program?

9. What do you think are the benefits of using iMonitor?

10. Are there any reasons why you should not use the program?

Needs

11. To what specific needs does iMonitor comply?

Skills

12. Which skills are needed to use iMonitor properly according to you?

13. Do you have those skills?

Self-efficacy

14. Do you think you are capable to use iMonitor correctly? Why?

Adherence

You received an email-alert in case a PROM/PROMs could be completed.

15. What are your experiences with receiving those alerts?

16. What do you think about the idea of receiving alerts?

17. To what extent do these email-alerts activate you to complete the PROM/PROMs?

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Social support

18. Are you supported by others (family, friends, peers) regarding the use of iMonitor?

    If yes: who and to what extent?

19. Do you talk with others about iMonitor? If yes, who?

20. How do you feel about receiving that social support?

Professional interaction

21. Do you/did you discuss the use of iMonitor with your rheumatologist or nurse specialist?

22. If yes, how do you/did you feel about that?

23. In case you attended the instruction class: What is your opinion about this instruction class?

Incentives and resources

Incentives/stimuli

24. In case you kept using the program: what made you keep using the program?

25. Which additional value do you experience by using iMonitor?

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Knowledge

26. Do you gain more knowledge by using the program?

    a. If yes, how and to what extent?

    b. If no, why not?

Time investment

27. What do you think about the time investment needed in order to use iMonitor?

Capacity for organizational change

28. Do you think that using iMonitor could contribute to a reduction in the number of outpatient consultations, and why? Or why not?

29. Do you have any recommendations in order to recruit more patients?

Social, political and legal factors

30. How do you think about the privacy standards regarding the use of iMonitor?

31. Have there been any issues you needed to solve?

Any additional information you want to share with us? Any comments or suggestions?

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