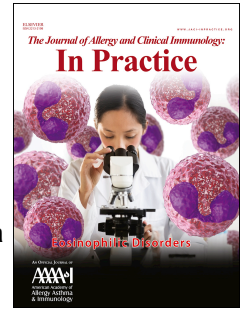


Journal Pre-proof

Effectiveness of myAirCoach: a mHealth self-management system in asthma

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PII: S2213-2198(20)30178-1

DOI: <https://doi.org/10.1016/j.jaip.2020.02.018>

Reference: JAIP 2711

To appear in: *The Journal of Allergy and Clinical Immunology: In Practice*

Received Date: 11 November 2019

Revised Date: 14 January 2020

Accepted Date: 10 February 2020

Please cite this article as: Khusial RJ, Honkoop PJ, Usmani O, Soares M, Simpson A, Biddiscombe M, Meah S, Bonini M, Lalas A, Polychronidou E, Koopmans JG, Moustakas K, Snoeck-Stroband JB, Ortmann S, Votis K, Tzovaras D, Chung KF, Fowler S, Sont JK, on behalf of the myAirCoach study group, Effectiveness of myAirCoach: a mHealth self-management system in asthma, *The Journal of Allergy and Clinical Immunology: In Practice* (2020), doi: <https://doi.org/10.1016/j.jaip.2020.02.018>.

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1 Effectiveness of myAirCoach: a mHealth self-management system in asthma

2

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22

23

24

25 Take home message: use of mHealth assisted self-management of asthma leads to improved control,
26 quality of life and reduced amount of severe exacerbations.

27

28 The trial was approved by the Medical Ethics Committee of Leiden University Medical Center and
29 North West - Greater Manchester South Research Ethics Committee. The trial was registered at
30 <http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=7200> with trial code NTR7200.

31

32 Abstract word count: 244

33 Main text word count: 3544

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35

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39 Funding: myAirCoach was funded by the European Commission in a Horizon2020 (H2020-EU.3.1.4.)
40 grant (Grant agreement ID: 643607).

41 Conflict of interest

42 Mr. Khusial has nothing to disclose. Dr. Chung reports grants and personal fees from
43 GlaxoSmithKline, personal fees from Astra-Zeneca, personal fees from Novartis, grants and personal
44 fees from Merck, personal fees from Boehringer Ingelheim, personal fees from TEVA, outside the
45 submitted work. Dr. Usmani reports grants and personal fees from Astra Zeneca, grants and
46 personal fees from Boehringer Ingelheim, grants and personal fees from Chiesi, personal fees from
47 Aerocrine, grants from GlaxoSmithKline, personal fees from napp, personal fees from Mundipharma,
48 personal fees from Sandoz, personal fees from Takeda, personal fees from Zentiva, grants from
49 Edmond pharma, personal fees from Cipla, outside the submitted work. Dr. Honkoop reports
50 personal fees from E-wise, outside the submitted work. Dr. Ortmann reports grants from European
51 Commission, during the conduct of the study; In addition, Dr. Ortmann, Dr. Votis and Dr. Tzovaras
52 have a patent DE 10 2016 219 759.2 pending. Ms. Meah has nothing to disclose. Dr. Simpson has
53 nothing to disclose. Dr. Biddiscombe has nothing to disclose. Dr. Koopmans has nothing to disclose.
54 Dr. Fowler has nothing to disclose.. Dr. Lalas has nothing to disclose. Dr. Polychronidou has nothing
55 to disclose. Dr. Moustakas has nothing to disclose. Dr. Snoeck-Stroband has nothing to disclose. Dr.
56 Soares has nothing to disclose. Dr. Sont research grants from AstraZeneca, outside the submitted
57 work.
58

59 **Abstract**

60

61 **Background**

62 Self-management programs have beneficial effects on asthma control, but their implementation in
63 clinical practice is poor. Mobile health (mHealth) could play an important role in enhancing self-
64 management.

65

66 **Objective**

67 To assess the clinical effectiveness and technology acceptance of myAirCoach supported self-
68 management on top of usual care in asthma patients using inhalation medication .

69

70 **Methods**

71 Patients were recruited in two separate studies. The myAirCoach system consisted of an inhaler
72 adapter, an indoor air-quality monitor, a physical activity tracker, a portable spirometer, a Fraction
73 exhaled Nitric Oxide (FeNO) device and an app. The primary outcome was asthma control; secondary
74 outcomes were exacerbations, quality of life, and technology acceptance. In study 1, 30 participants
75 were randomized to either usual care or myAirCoach support for 3-6 months; in study 2, 12
76 participants were provided with the myAirCoach system in a 3 month before-after study.

77

78 **Results**

79 In study 1 asthma control improved in the intervention group compared to controls (ACQ difference
80 0.70, $p=0.006$). A total of six exacerbations occurred in the intervention group compared to 12 in the
81 control group (hazard ratio 0.31, $p=0.06$). Asthma related quality of life improved (m-AQLQ
82 difference 0.53, $p=0.04$), but FEV1 was unchanged. In study 2, asthma control improved by 0.86
83 compared to baseline ($p=0.007$) and quality of life by 0.16 ($p=0.64$). Participants reported positive
84 attitudes towards the system.

85

86 **Discussion**

87 Using the myAirCoach support system improves asthma control and quality of life, with a reduction
88 in severe asthma exacerbations. Well validated mHealth technologies should therefore be further
89 studied.

90

91 Highlights

92 1. What is already known about this topic?

93 The use of eHealth/mHealth in asthma care is upcoming. Many different apps and systems
94 are currently available, however most systems are not evaluated in a scientific setting.

95 2. What does this article add to our knowledge?

96 This study shows mHealth has the potential to positively influence asthma-related
97 outcomes. Patients are also satisfied using mHealth.

98 3. How does this study impact current management guidelines?

99 mHealth has the potential to transform health care delivery and should therefore be
100 included as an effective option in future guidelines to support self-management.

101

102 Key words: asthma, mHealth, app, eHealth, telemedicine, self-management, quality of life,
103 personalized care

104

105	List of abbreviations
106	
107	ACD- Asthma Control Diary
108	ACQ- Asthma Control Questionnaire
109	Apps- mobile applications
110	CI- Confidence Interval
111	EQ-5D-5L- EuroQol-5 Dimensions-5 Levels questionnaire
112	FEV1- Forced Expiratory Volume in 1 second
113	FeNO- Fraction exhaled Nitric Oxide
114	IQR- Inter Quartile Range
115	ppb- parts per billion
116	PM2.5- Particulate Matter 2.5
117	PM10- Particulate Matter 10
118	m-AQLQ- mini Asthma-related Quality of Life Questionnaire
119	MCID- Minimal Clinically Important Difference
120	MDI- Metered Dose Inhaler
121	NO2- Nitric dioxide
122	SD- Standard Deviation
123	SNOT-22 - Sino-Nasal Outcome Test-22
124	SO2- Sulphur Dioxide
125	TAQ- Technology Acceptance Questionnaire
126	

127 Introduction

128 Self-management plays an important role in treatment for asthma (1). Effective self-management
129 allows patients to use medication and devices correctly, acknowledge importance of lifestyle and
130 environmental influences, recognize aggravating factors and understand the value of self-
131 monitoring. Additionally, patients need to be able to recognize and treat worsening of symptoms
132 and know when to seek urgent medical attention (2). Therefore, asthma action plans are advised to
133 support patients in evaluating and managing their symptoms (1).

134 However, patient adherence to self-management programs is low, with only 20% of people
135 reporting the use of an action plan (3). Self-management tasks are often regarded as burdensome
136 and time-consuming while patients indicated that they would prefer different data to be added to
137 their asthma action plan (4). Current action plans based solely on symptoms and/or lung function
138 parameters also lack precision in detecting deteriorations in asthma control and asthma
139 exacerbations (5). Preferably automatically collected data could improve both precision and
140 acceptance.

141 Mobile health (mHealth) support has the potential to transform health care delivery (6). Home-
142 monitoring applications involving mobile device-based interactive systems are promising tools for
143 overcoming the above mentioned barriers and supporting self-management of asthma (7). mHealth
144 can now integrate physiological, behavioral and environmental information to aid self-management.
145 Therefore, mHealth could encourage patients to be more engaged in self-management activities,
146 given the ease of use of their own mobile phone.

147 There are over 500 mobile phone applications (apps) for asthma (8), but scientific evidence
148 supporting the majority of these apps is lacking and their quality varies greatly (8, 9). Development
149 and promotion of such apps presently does not appear to require evidence that they indeed improve
150 asthma outcomes (10), which makes it difficult for patients and healthcare to choose the correct and
151 effective apps for their own use (11). Huckvale reported in 2015 that 13% of the available asthma
152 apps made recommendations about self-care procedures that were not based on scientific evidence
153 (12). Importantly, non-evidence-based apps used as medical tools are potentially harmful (13).

154 Therefore, the objective of the myAirCoach project was to create a validated app, that would contain
155 elements deemed necessary by patients to aid self-management (14). We have previously reported
156 on patients' views on the required content of an asthma-related mHealth system (4) and assessed
157 the feasibility and end-user experience of physiological and behavioral data collection, using already
158 available mHealth and home-monitoring tools (15).

159 Data from these studies were used by the myAirCoach consortium (www.myaircoach.eu) to develop
160 a mHealth system, which included an app and several portable devices, to integrate support for
161 important self-management aspects and tasks. The system presented data to the participant on
162 factors, including asthma control, inhalation technique and environment exposure, thus providing
163 patients with a wider insight into their condition and how it is affected by their environment and
164 behavior.

165 In this study we assessed the clinical effectiveness of the mHealth supported myAirCoach self-
166 management system in patients with asthma compared to usual care and present the results of two
167 linked and simultaneously performed studies.

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168 Methods**169 Setting and participants**

170 The myAirCoach project was EU Horizon2020 funded and conducted by a research consortium of 12
171 collaborating partners (list of partners available at www.myaircoach.eu). Study 1, a pragmatic
172 randomized controlled trial, registered at www.trialregister.nl (NTR 7200), was originally planned to
173 be performed in the Netherlands and two sites in the United Kingdom (UK). The study was approved
174 by the Medical Ethics Committee of Leiden University Medical Center and North West - Greater
175 Manchester South Research Ethics Committee.

176
177 The original sample-size calculated was based on the Asthma Control Questionnaire (ACQ). In order
178 to detect a difference of 0.5 (SD 0.8) points with an alpha error of 0.05 and a power of 80%, the
179 minimum sample-size needed was 41 subjects per group, 82 in total. Due to delays in obtaining
180 ethical and MHRA approval in the UK, the UK part of the study was changed to a before-after study
181 (study 2).

182
183 Participants in both studies were eligible if they: had a clinical diagnosis of asthma; were treated
184 with controller medication with a metered dose inhaler (GINA treatment step 2-5 (1)); had a current
185 status of asthma with an Asthma Control Questionnaire (ACQ)-score of ≥ 1.5 (16) and/or ≥ 1
186 exacerbations or hospital visit due to asthma in the previous year; were 18 years or older; and were
187 able to understand Dutch or English in the respective countries. All participants provided written
188 informed consent.

189 Design overview

190 Study 1 was a pragmatic randomized controlled trial in the Netherlands. Participants were included
191 over a period of four months, while we used a fixed end date for all participants, resulting in a varied
192 follow-up duration (3-6 months). Participants were randomized by a computerized algorithm to
193 receive either 'usual care' or 'usual care + self-management support via myAirCoach'. Study 2 was a
194 3 month before-after study in the UK in which all participants used the myAirCoach system.

195 All participants attended the research facility twice; once for a 30 minute introductory meeting and
196 again at the end of the study. During these visits participants completed questionnaires and lung
197 function (FEV1), and fraction of exhaled nitric oxide (FeNO) were measured. Participants in the
198 intervention group in study 1 and all participants in study 2 were given instructions on how to use
199 the myAirCoach app and different devices for self-management support, lasting approximately 1
200 hour. In addition, all participants received periodical questionnaires through email to assess
201 outcome parameters (see online repository). All participants continued care with their usual
202 caregiver.

203 Intervention

204 The intervention was developed based on the outcomes of the focus group study and experiences of
205 participants in the observational study (4, 15). During the development phase the research
206 consortium had joint meetings with patient advisory forums in order to obtain feedback and

207 prototype improvements were made accordingly. The final integrated system consisted of several
208 devices and an app.

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210 *Devices*

211 Both an inhaler adapter and indoor air quality monitor were designed and produced by the
212 myAirCoach study consortium. The inhaler adapter was an add-on which fitted different sized
213 Metered Dose Inhalers (MDI's), with or without spacer and it connected to the myAirCoach app
214 through Bluetooth. The inhaler adapter (see online repository figure E8) was developed to improve
215 inhalation technique. It measured correct positioning of the inhaler during inhalation by an
216 accelerometer. Feedback was provided with the use of indicator LED's (red and green) on top of the
217 inhaler adapter. In parallel, the inhaler adapter recorded sound for 24 seconds with the use of a
218 built-in microphone. Sound analysis was performed on the order of actions (inhaling, actuation and
219 exhaling) (17). Based on accelerometer results and sound analyses, an Inhaler Technique Score
220 between 0-100 was calculated and provided to the participant in the myAirCoach app directly after
221 use. If the Inhaler Technique Score was less than 100%, feedback on what could be improved was
222 provided and the participant was redirected to an in-app manual for correct inhalation technique.

223 The indoor air quality monitor (see online repository figure E10), registering nitrogen dioxide (NO₂),
224 Sulphur dioxide (SO₂), particulate matter (PM_{2.5} and PM₁₀), humidity, air pressure and
225 temperature, was placed in the bedroom. Data, recorded every hour, was transmitted by Bluetooth
226 to the smartphone of the participant and results were displayed in the myAirCoach app.

227 Participants could monitor their FEV₁ with a portable spirometer (nSpire Health, PiKO-1 device;
228 available at www.nspirehealth.com) and FeNO with a home sensor (Aerocrine, NIOX VERO device;
229 available at www.niox.com). The results were shown on the displays of the devices and participants
230 were asked to manually enter results in the app.

231 The Fitbit Charge HR (Fitbit, Inc, Fitbit charge HR; available at <http://www.fitbit.com>) is a wearable
232 fitness tracker, measuring steps and stairs walked, calories burned and real-time heart rate.
233 Participants were advised to wear the Fitbit continuously. Heart rate and steps data were shown in
234 the myAirCoach app.

235
236 *myAirCoach app*

237 At the first visit, participants downloaded the myAirCoach app on their smartphone. Since the app
238 was only used in a research setting and required anonymity, the app was not publicly available, but
239 could only be downloaded with the help of the research team. Every participant was also given an
240 anonymous username and password and logging in was required the first time they used the app. In
241 the app, results from all devices were displayed in graphs. Additionally, participants were able to
242 monitor symptoms with questionnaires, including the Asthma Control Diary (ACD) (18), Asthma
243 Control Questionnaire (ACQ) (19) and Sino-Nasal Outcome Test-22 (SNOT-22) (20) (see online
244 repository table E2). Outdoor air quality, measured by the European Copernicus Program
245 (www.regional.atmosphere.copernicus.eu), was also displayed for current location or other favorite
246 locations. A map using color-coding to indicate levels of pollution was provided in addition to an
247 overall statement on air pollution and concentrations of ozone, ultra-fine dust, fine dust, carbon
248 monoxide, NO₂ and SO₂. More detailed information on the app and devices is provided in the online
249 repository (including figure E4-E9).

250

251 Outcomes and follow-up

252 For both studies the primary outcome was asthma control assessed by the Asthma Control
253 Questionnaire (ACQ, range 0-6; Minimal Clinically Important Difference (MCID) = 0.5) at 4-week
254 intervals (19). A lower score represents better asthma control.

255 Secondary outcomes were severe asthma exacerbation rate, quality of life, FEV1 and technology
256 acceptance. Severe exacerbations were defined as asthma-related hospitalizations, emergency care
257 visits or systemic use of oral corticosteroids for ≥ 3 days (21). Asthma related quality of life was
258 measured by the mini Asthma Quality of Life Questionnaire (m-AQLQ; MCID = 0.5 (22)), consisting
259 of four domains: symptoms, activities, emotions and environment, at 12-week intervals. Generic
260 health-related quality of life was assessed by the EQ-5D-5L questionnaire at 12-week intervals (23).
261 FEV1 was measured with the PiKO-1 device throughout the study for the intervention participants
262 and during the visits for the controls. Participant attitudes towards and acceptance of the
263 technology were measured by the Technology Acceptance Questionnaire (TAQ) at 12-weeks (24).
264 The TAQ has eleven domains next to specific questions about the inhaler adapter and the PiKO-1
265 device (see online repository).

266

267 Statistical analysis

268 In study 1 the outcomes of the ACQ, m-AQLQ, EQ-5D-5L and FEV1 were analyzed using a mixed
269 model analysis, adjusting for repeated measurements within participants, and baseline values of the
270 outcomes. Severe exacerbation rates were compared by the Cox proportional hazard model,
271 allowing analysis of multiple exacerbations per participant. For study 2 paired t-tests were
272 performed for the ACQ, m-AQLQ, EQ-5D-5L and FEV1 comparing baseline measurements with the
273 final results. Boxplots for the TAQ were made, combining results of all participants using the system
274 in both study 1 and 2. All analyses were performed with STATA 14.0 (StataCorp, College Station, TX).

275

276 **Results**277 *Subjects*

278 Thirty participants were included in study 1 and twelve participants in study 2 (see online repository
279 figure E1). The major reason for declining participation was concern about time. Two participants
280 dropped out of study 1, one in the intervention group due to 'personal circumstances' and one
281 control (no further response to repeated enquiry). Mean follow-up in the intervention group was
282 166 days and in the control group 154 days. All participants from study 2 finished follow-up with a
283 mean follow-up of 94 days.

284 Baseline characteristics are shown in table 1. There were no significant differences between control
285 and intervention groups in study 1. Participants in study 2 had a slightly different profile than
286 participants of study 1. They were on average 10 years younger, their age of diagnosis was also
287 lower, FeNO was higher and their baseline ACQ was better.

288 *System use*

289 The app was used for 2345 tasks. These tasks included filling out questionnaires and entering
290 FeNO/FEV1 data (see online repository table E1). In study 1 on average 110 tasks per patient were
291 performed and in study 2 this was on average 67 times.

292 The number of inhalation registered by the system in study 1 was 219 inhalations/patient and in
293 study 2 this was 81 inhalations/patient. In study 1 the Inhaler Technique Score changed by 1% (from
294 79% to 80%). In study 2 the Inhaler Technique Score changed from 88% to 76%.

295 *Outcomes*

296 The intervention group had a clinically relevant and statistically significant improvement of asthma
297 control compared to the control group in study 1. In the mixed-model analysis, the difference in ACQ
298 was 0.70 (95%CI -1.21; -0.20, $p=0.006$) (table 2). A sensitivity analysis additionally adjusting for
299 baseline characteristics age, smoking status, age of diagnosis and gender and a sensitivity analysis
300 for baseline FEV1 and FeNO showed similar results. In study 2 asthma control improved by 0.86
301 (95%CI 0.29; 1.44, $p=0.007$) compared to baseline, as shown in figure 1.

302 The number of severe exacerbations was lower in the intervention group compared to the control
303 group for study 1 (respectively, 6 vs 12 (hazard ratio 0.31, 95%CI 0.09; 1.06, $p=0.06$), see figure 2).
304 Exacerbation rate for intervention participants was 0.94 per participant per year, compared to 2.04
305 per participant per year for the participants in the control group. In study 2, three exacerbations
306 occurred. Exacerbation rate was 1.06 per participant per year.

307 The difference in m-AQLQ assessed by the mixed-model analysis was 0.53 (95%CI -0.22; 1.10,
308 $p=0.04$) (figure 3). The differences in the subdomains 'symptoms' and 'emotions' both exceeded the
309 MCID of 0.5 and were statistically significant (online repository table E3; figure E11). In study 2, the
310 participants had a baseline m-AQLQ of 5.13 and their score increased by 0.16 ($p=0.64$). The
311 participants improved in all domains, with the largest improvement in the 'emotions' domain.

312 The EQ-5D-5L showed an improvement in generic health-related quality of life in the intervention
313 group (coefficient 0.12, $p=0.04$) in study 1 compared to the controls. In study 2 there was no

314 significant difference in EQ-5D-5L score between baseline and exit (0.04, $p=0.23$), as shown in figure
315 E2.

316 There was no change in FEV1 measured in both studies. In study 1 the FEV1 was 0.09 liters ($p=0.60$)
317 lower in the intervention group compared to the control group (see figure E3). In study 2
318 participants had a baseline FEV1 of 2.63L and their exit FEV1 was 2.52L ($p=0.42$).

319 The TAQ showed favorable attitudes of the participants towards the myAirCoach intervention
320 except for the impact of the system on social influence and attitude towards the inhaler adapter.
321 Participants were most positive on the facilitating conditions and trust in the system. They also
322 reported favorable attitudes on the self-management aspect of the system. The average domain
323 scores are depicted in the figures below (Figure 4).

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324 **Discussion**

325 Our study shows that mHealth supported self-management aided by the myAirCoach system was
326 effective in clinically improving asthma control, exacerbation-rates and quality of life. Additionally,
327 end-users of this mHealth platform reported generally positive attitudes towards the system.

328 In asthma, most research in eHealth has focused on using traditional forms of telemedicine,
329 including remote consultations and SMS reminders (25-27). Even though Huckvale et al. already
330 reported 764 different asthma apps in 2015 (12), the number of trials focusing on mobile app
331 assisted self-management in asthma is limited (28). Moreover, none of the apps assessed in previous
332 studies additionally used such diverse data from wearables, environmental databases and home-
333 monitoring devices (29). As a consequence of our multi-faceted intervention, we opted to assess
334 clinical outcomes, such as asthma control and exacerbation rate. Other studies have focused more
335 on outcomes particularly relevant for medication adherence. For example, the recent ADAPT study
336 by Kosse et al. developed an app with several modules primarily targeting adherence in adolescents
337 and they showed that their app indeed improved this (30).

338 A Cochrane review in 2012 (updated in 2013) included only two studies regarding asthma self-
339 management with apps compared to paper-based asthma self-management (31). Ryan et al.
340 concluded that monitoring of asthma through mobile phone use does not improve asthma outcomes
341 more than paper based strategies (32). Both groups showed clinically relevant improvements in
342 asthma control and quality of life. It is suggested that monitoring in itself could have a positive effect
343 on asthma related outcomes. However, paper monitoring could be more cumbersome and time-
344 consuming for the participant and it does not allow for collection of other types of data, such as
345 heart rate. mHealth is more user-friendly since a majority of the adults uses a smartphone (33).

346 A study by Cook was a promising proof of concept study showing the effectiveness of an asthma
347 related mHealth application (34). The asthma related outcomes (asthma control and FEV1) improved
348 and patients were satisfied with the intervention. This study however only consisted of an
349 intervention group without randomization. Our study supports and extends these findings since we
350 have found a beneficial effect on asthma control, severe asthma exacerbations and quality of life
351 and we included a control group in the first study to minimize the effect of confounding factors
352 unrelated to the mHealth. We also reported a high user-satisfaction.

353 An important aspect of the myAirCoach project was the involvement of participants in different
354 stages of the development of our intervention, including repeated device testing to improve
355 performance. We specifically asked what kind of functionalities they wanted to see in a mHealth
356 system and what they deemed useful information. If no device existed that could measure these
357 parameters, we developed it within our study consortium. Overall, the participants were satisfied
358 with the system and they reported they felt the system aided them in their self-management. We
359 believe that this early involvement of patient users in this project has helped in devising a user-
360 friendly tool for self-management of asthma.

361 An important strength of our study is that we provided participants with an app which included a
362 wide variety of data on very different aspects of asthma management. The app was used often, with
363 110 tasks per patients on average in study 1 and 67 tasks per patient in study 2. We were only able
364 to record a task if the participant manually entered data into the app (answering a questionnaire,

365 entering a measurement). So, the average numbers of tasks indicates the minimal usage, since any
366 other action in the app (e.g. viewing of inhalation score, air quality data or individual graphs on
367 symptoms and measurements) was not recorded.

368 Although we showed that by providing a comprehensive overview we managed to improve asthma
369 control, exacerbation rate and quality of life, we do not know how much each of the individual
370 components contributed to these improvements. This also relates to the fact that we did not record
371 viewing of results in the app of, for example, the inhalation technique score. We know this improved
372 in some and worsened in others. However, we do not know who actually viewed their inhalation
373 technique results in the app, or who acted upon these results, for example by viewing the in-app
374 inhalation instructions or by going to their healthcare professional. Different components are
375 relevant for different patients. In future studies we recommend to also systematically collect data on
376 page-views and time spent on different components of an app and preferably also on subsequent
377 self-management changes made by patients.

378 An important limitation of the study is the number of participants included in the study. In the
379 original protocol the intention was to include 90 participants in the study (45 intervention and 45
380 control). Due to the fixed end date of the study appointed by the EU, combined with strict regulatory
381 laws regarding studies with medical devices in the UK and longer than expected development time
382 of the app and devices, we were only able to include 30 (randomized) participants in the study site in
383 the Netherlands. All UK participants were allocated to the use of the myAirCoach system in order to
384 get as much feedback on the system as possible in a before-after study setting. Even though the
385 amount of participants included in the RCT was limited, the primary outcome parameter improved.
386 One might argue that this might be due to overestimation of the real effect, also known as the
387 winner's curse. However, since most secondary outcomes also showed a consistent improvement
388 and the effect was still statistically significant after correction for multiple tests we are confident
389 that the myAirCoach system had a positive effect on asthma related outcomes.

390 Another limitation is the lack of long-term data of the system. Participants in the Netherlands used
391 the system for a maximum of 6 months. Even though participants reported in the TAQ that they
392 were willing to continue using the system, it is unknown if the positive effects on asthma control
393 would be sustained after a longer period. Another important aspect is the influence of seasonal
394 factors on the results of our study, since we do not have a year follow-up time. Next, in 74% of the
395 inhalation no inhalation technique score could be calculated due to technical issues, possibly
396 explaining the negative attitudes of the patients towards the inhaler add-on in the TAQ.

397 Even though the age of participants was highly variable (23 to 77 years old), future studies are called
398 for to further evaluate mHealth systems in larger and more diverse groups. In future projects
399 predictive modelling could be used to make personalized recommendations given by the system to
400 further enhance self-management.

401

402 **Conclusion**

403 We have shown a clinically significant beneficial effect of the myAirCoach mHealth intervention on
404 asthma related outcomes. Asthma control, quality of life and exacerbation-rate improved during the
405 study. Overall, participants were satisfied with the myAirCoach study app and intervention.

406 **Data availability**

407 Data analyzed in this manuscript are available upon request.

408

Journal Pre-proof

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492

493 **Figure legends**

494

495 **Fig. 1 Asthma Control Questionnaire**

496 Asthma control measured by ACQ. Lower score represents better asthma control (MID=0.5). Note:
497 not all participants finished 6 months follow-up due to a fixed end date ; mean follow-up was 149
498 days (5 months) in study 1. A questionnaire filled in within 14 days of enrollment is regarded as
499 baseline. In study 1, 28/30 participants finished 12 weeks follow-up and 5 participants (17%) had
500 more than 24 weeks follow-up. Error bars represent 95%CI. Points in the graph have been shifted
501 slightly to the left or the right in order to avoid overlap of error bars.

502

503 **Fig. 2 Time until first exacerbation per participant**

504 Proportion exacerbation plotted against follow-up time. The numbers depicted in the graph indicate
505 the participants still in follow-up.

506

507 **Fig. 3 Mini Asthma Quality of Life Questionnaire**

508 Asthma related quality of life measured by the m-AQLQ. Higher score represents better quality of
509 life (MID=0.5). Note: not all participant finished 6 months follow-up in study 1. Error bars represent
510 95%CI. Points in the graph have been shifted slightly to the left or the right in order to avoid overlap
511 of error bars.

512

513 **Fig. 4 Boxplots of the Technology Acceptance Questionnaire domains**

514 Thirteen domains of the Technology Acceptance Questionnaire tested in both studies combined.
515 Patients reported how much they agreed with the questionnaire statements on a 7-point Likert scale
516 (ranging from completely disagree =1 to completely agree =7). The higher a score, the more
517 favorable the attitudes of the participants towards the myAirCoach system were. In the figure all 13
518 domains are plotted and the scores are depicted on the y-axis of every boxplot.

519

520

521 **Table 1. Participant demographics**

	Study 1 (RCT in the Netherlands)			Study 2 (before-and-after study in the UK)
	Control (n=15)	Intervention (n=15)	p value	(n=12)
Age, mean (SD) years*	49.1 (11.0)	51.3 (13.2)	0.65	41.3 (13.8)
Gender, n female*	11	12	0.68	10
Internet experience, n**			0.27	
• None	0	1		
• A little	1	1		
• Quite a lot	2	6		2
• A lot	11	7		10
Smoking, n**			0.14	
• Yes	0	0		1
• No	11	7		10
• Previously	4	8		1
Season enrolled, n**			0.66	
• Winter	2	1		0
• Spring	11	13		0
• Summer	2	1		12
GINA medication step, n**			0.25	
• 2	0	3		1
• 3	8	6		2
• 4	0	1		1
• 5	2	2		
Severe exacerbations previous year, n **	13	14	0.54	8
Age at diagnosis, mean (SD) years*	26.1 (18.6)	19.5 (21.1)	0.39	16.4 (18.4)
FEV1, median (IQR) L***	2.3 (1.4-2.9)	2.1 (1.5-3.0)	0.85	2.5 (1.9-3.4)
FeNO, median (IQR), parts per billion***	18 (13-28)	14 (12-22)	0.45	17 (11.5-54)
ACQ, mean (SD) score*	2.31 (0.97)	2.33 (0.78)	0.94	1.59 (0.88)
• Controlled (n)	0	0		3
• Partly controlled (n)	3	3		3
• Uncontrolled (n)	11	11		6
SNOT22, mean (SD) score*	35.9 (18.4)	40.4 (17.9)	0.52	27.9 (12.0)

522 * calculated with t-test

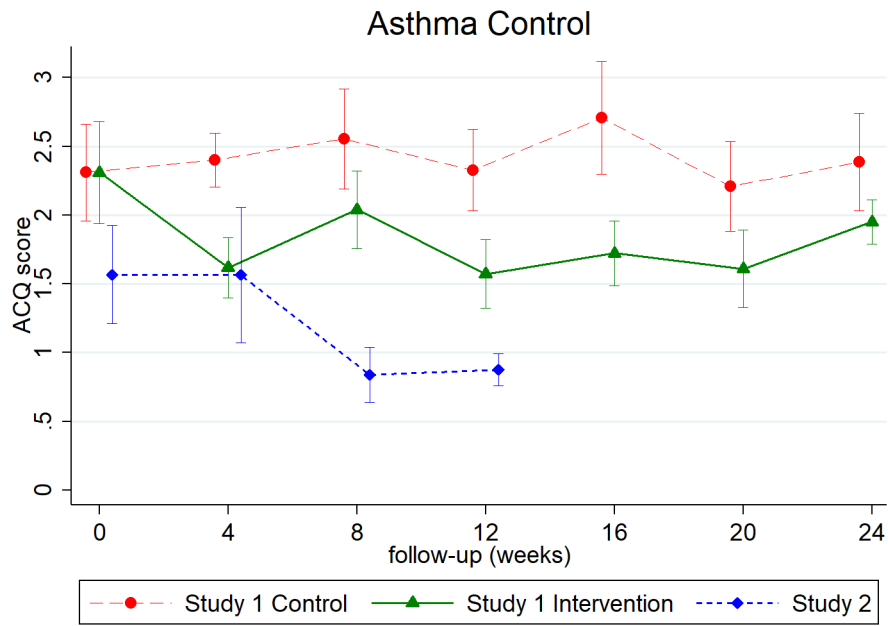
523 **calculated with chi²

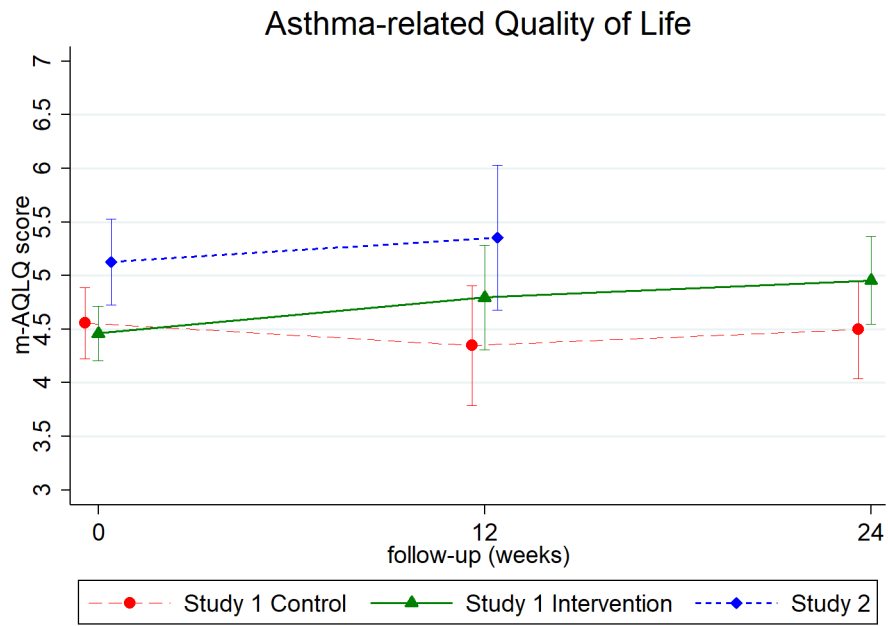
524 ***Mann-Whitney U test

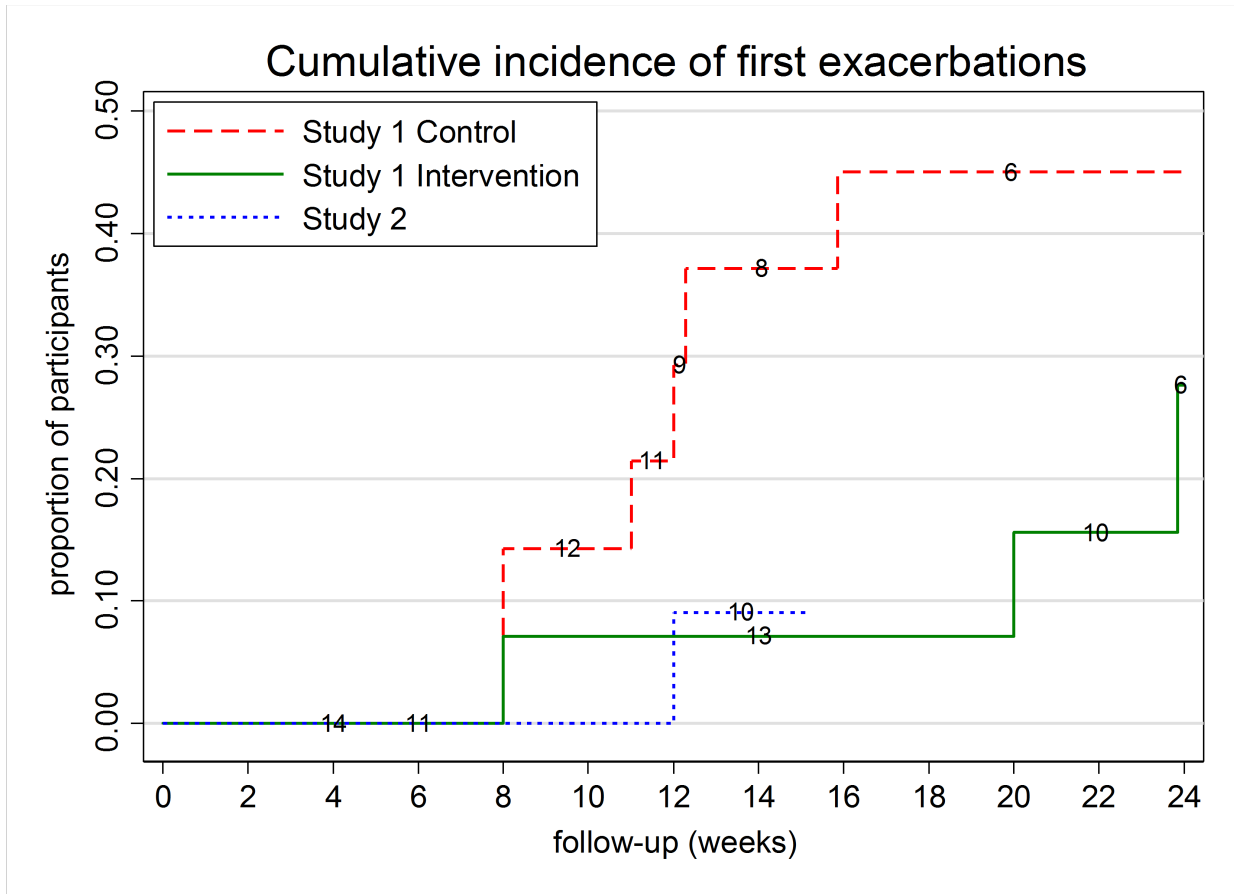
525 **Table 2. Outcome measures.**

	Study 1		Study 2	
	Difference intervention-control	<i>p</i> value	Difference exit-baseline	<i>p</i> value
ACQ , score	-0.70	0.006	-0.86	0.007
m-AQLQ, score	0.53	0.04	0.16	0.64
EQ-5D-5L, score	0.12	0.04	0.04	0.23
FEV1, liters	-0.09	0.60	-0.11	0.42

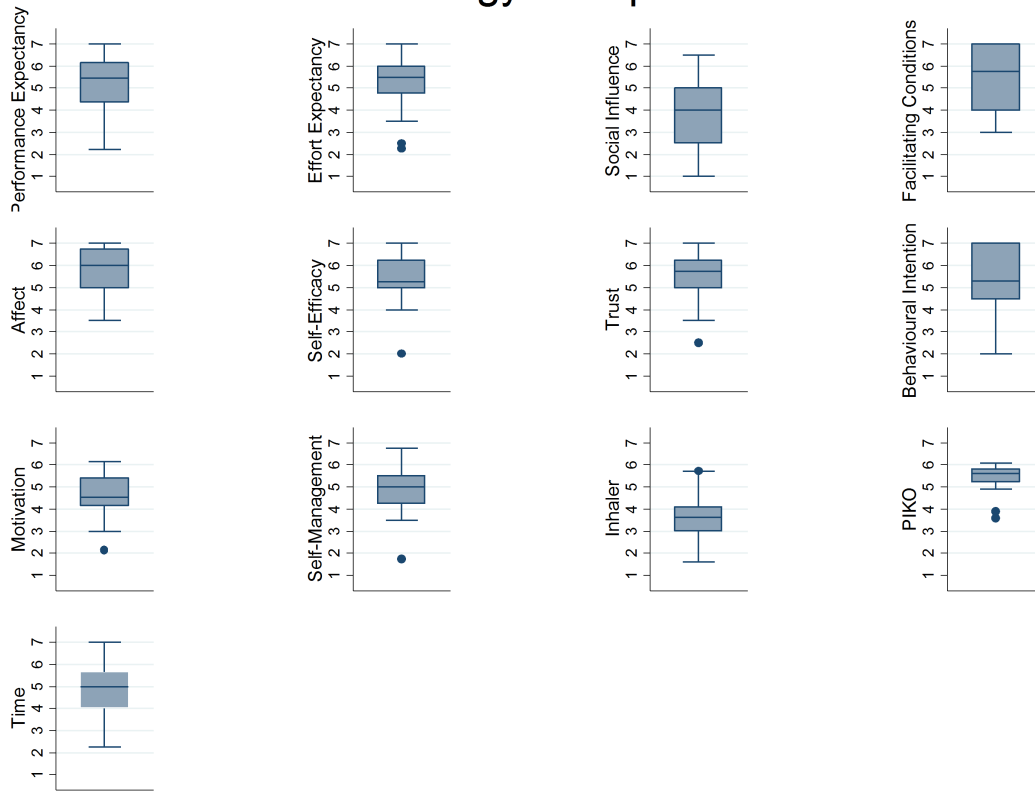
526 Differences as assessed by mixed model analysis, adjusting for repeated measurements within
527 participants, and baseline values of the outcomes.







Technology Acceptance



Online Repository Text

Flowchart participant inclusion

Journal Pre-proof

Generic health-related Quality of life

Journal Pre-proof

Lung function

Journal Pre-proof

Devices and app

The app could be downloaded if the participant had an android phone. If participants used Apple's iPhone, the app could not be installed on their smartphone since every iPhone is linked with a personal Apple account (Apple ID), which prevents anonymous processing of data, because all recorded data is also shared with Apple. Therefore, participants with an iPhone were given an iPod Touch with an anonymous Apple ID specifically created for this study. The iPod Touch was a 6th generation iPod that works in a similar fashion as the iPhone these participants normally used.

When the app was opened, participants could navigate to one of the five menu's: 'Dashboard', 'Measurements', 'Calendar', 'Messages' and 'Me'. The menu 'Dashboard' (figure E4) was divided into five tabs (at the top of the screen) of which 'At a Glance' was the main screen. Here participants could see a quick summary of the most recent measurements in a general overview. In the second screen named 'Action Plan' an asthma action plan was shown to the participants. In the third tab 'Questionnaires' participants could fill out the ACD, ACQ or SNOT22 questionnaires. The following two tabs 'Goals' and 'Notifications' allowed participants and health care providers to set personalized goals (for example: amount of steps a day) and receive (update) notifications. In the screenshots below demo scores are depicted as an illustration.

The second menu at the bottom was 'Measurements' (figure E5), which was divided in three main categories: 'Health', 'Activity' and 'Environmental'. In 'Health' participants could see an overview of their personal scores of Inhaler Use, FeNO, Spirometry and their questionnaires (ACD/ACQ, SNOT22). In 'Activity' participants could see an overview of their Fitbit data. In 'Environmental' participants were able access air quality data for outdoor air quality (www.regional.atmosphere.copernicus.eu) and indoor air quality (measured by the Indoor air quality monitor).

Participants could select every individual measurement to see an overview over time (see figure E6). Mean scores were calculated and displayed in a visual manner. More detailed information about individual measurements was available by pressing the 'all data' button.

In the 'Calendar' participants were shown measurements in a Calendar to more easily identify days with worse (or better) asthma control, as well as to have a complete overview and history of their actions. Participants could also manually enter notes about specific events in order to facilitate in recollecting these details when discussing their asthma with a healthcare professional a few months later (a feature specifically requested by participants) (4).

In the 'Messages' tab participants could chat in real-time with the research team. In possible future projects participants could use this function to chat with their own healthcare provider. The final tab 'Me' was a settings function with guides for the app, inhalation technique instruction material and links to useful websites on asthma. In this tab participants could also enable or disable the virtual support "Airica" (figure E7) which recognized voice commands and text inputs. Airica is based on artificial intelligence, such as machine learning algorithms and natural language processing concepts.

The inhaler add-on shown in the picture below (figure E8) was an add-on to normal MDI's. After activation the device by shaking it, it connected to the app. A screen would pop-up and sound recording would start, which is shown in figure E9 . After sound recording was finished, data was

uploaded, processed and then sent back to the app. A score was calculated varying from 0% to 100% and displayed to the participant.

The indoor air quality monitor (air quality sensor) was a black cube connected through Bluetooth with the smartphone and the app. It was roughly 7cm x 7cm x 7cm (figure E10). Data was recorded every hour, temporarily stored on an internal memory and transmitted to the phone when available. Participants were asked to hold their smartphone at least daily within Bluetooth vicinity of the indoor air quality monitor to allow data transfer.

Table E1. Number of times the app was used to perform tasks.

	Study 1	Study 2	Total
ACD	130	177	307
ACQ	70	27	97
Feno	570	213	783
SNOT22	67	34	101
Spirometry	700	357	1,057
Total	1,537	808	2,345

Activities

Participants were asked to fill out questionnaires and do measurements frequently. Questionnaires not described in this manuscript are: the Food Frequency Questionnaire (GA2LEN FFQ), Hospital Anxiety and Depression Scale (HADS), Health Education Impact Questionnaire (heiQ), Sino-Nasal Outcome Test (SNOT-22) and Cost-Q. The Asthma Control Diary (ACD) is a questionnaire comparable to the ACQ, except it asks questions about the previous day (compared to the previous week).

Table E2. Study procedures

Frequency of tests	First visit	INTERVENTION		CONTROL		Final visit
		1-2 wk training phase	Follow-up	1wk test phase	Follow-up	
<u>Patient Questionnaires</u>						
ACD or ACQ	<i>Once</i>	<i>Daily</i>	<i>Monthly</i>	-	<i>Monthly</i>	<i>Once</i>
Current medication record	<i>Once</i>	<i>Daily</i>	<i>Monthly</i>	-	<i>Monthly</i>	<i>Once</i>
Exacerbations history	<i>Once</i>	<i>Daily</i>	<i>Monthly</i>	-	<i>Monthly</i>	<i>Once</i>
m-AQLQ	<i>Once</i>	-	<i>3-monthly</i>	-	<i>3-monthly</i>	<i>Once</i>
GA ² LEN FFQ	<i>Once</i>	-	-	-	-	-
HADS	<i>Once</i>	-	-	-	-	-
heiQ	<i>Once</i>	-	<i>3 months</i>	-	<i>3 months</i>	<i>Once</i>
SNOT-22	<i>Once</i>	-	<i>Monthly</i>	-	<i>Monthly</i>	<i>Once</i>
EQ-5D-5L	<i>Once</i>	-	<i>3-monthly</i>	-	<i>3-monthly</i>	<i>Once</i>
Cost-Q	-	-	<i>3-monthly</i>	-	<i>3-monthly</i>	<i>Once</i>
Technology Acceptance Questionnaire		-	<i>3 months</i>	-	-	<i>Once</i>
<u>Physiological sensors</u>						
Portable spirometry	<i>Once</i>	<i>Daily</i>	<i>Weekly</i>	-	-	-
FeNO	<i>Once</i>	<i>Daily</i>	<i>Weekly</i>	-	-	<i>Once</i>
Heart Rate and activity level	<i>Once</i>	<i>Continuous</i>	<i>Continuous</i>	-	-	-
<u>Monitors</u>						
Inhaler usage monitoring	<i>Once</i>	<i>Continuous</i>	<i>Continuous</i>	-	-	-
External environmental monitoring	-	<i>Continuous</i>	<i>Continuous</i>	-	-	-

m-AQLQ domains

The m-AQLQ can be divided in 4 domains: symptoms, activities, emotions and environment (Table E3; figure E11) . In study 1 improvements in ‘symptoms’ and ‘emotions’ were both clinically and statistically significant. Improvements in the ‘environments’ domain also exceeded the MCID.

Table E3. Quality of life per domain.

Domain	Study 1*		Study 2†	
	Difference	P value	Change	P value
• symptoms	0.69	0.03	0.22	0.51
• activities	0.32	0.41	0.10	0.83
• emotions	0.54	0.04	0.25	0.44
• environment	0.53	0.08	0.03	0.94

*study 1. RCT: intervention compared to controls with mixed-model analysis

† study 2. Before-and-after study: baseline compared to end of follow-up with paired t-test

Technology Acceptance Questionnaire (TAQ)

The twelve domains of the TAQ are:

- Performance expectancy: the degree to which participants believe that using the system will help them attain gains or make losses with the performance of their health management
- Effort expectancy: the degree of ease associated with the use of the system
- Social influence: the degree to which participants perceive that important others believe they should use the system
- Facilitating conditions: the degree to which participants believe that there are objective factors available in their environment to support their use of the system
- Affect: participants' overall affective reaction towards using the system
- Self-efficacy: the degree to which participants judge themselves capable of using the system to manage their health
- Trust: the degree to which participants believe that using the system will occur in a safe and reliable manner
- Behavioral intention: the degree to which an individual intends to use of the myAirCoach system for managing their health
- Motivation: the degree to which an individual is motivated to continue the myAirCoach system for managing their health
- Self-management: participants' opinion on conducting self-management through the system
- Inhaler adapter: participants' opinion on the myAirCoach inhaler adapter
- PiKO-1: participants' opinion on the PiKO-1 home spirometer
- Time: the degree to which an individual is satisfied with the amount of time it takes to use the system

Captions

Fig. E1 Flowchart participant enrollment

Study 1 is shown on the upper panel (A) and study 2 on the lower panel (B).

Fig. E2 EQ-5D-5L

Generic health-related quality of life measured by the EQ-5D-5L questionnaire.

Fig. E3 FEV1

Home-measured FEV1 by the intervention patients in study 1 and patients from study 2 with use of the PiKO-1.

Fig. E4 myAirCoach app: Dashboard

Different aspects of the myAirCoach app: 'At a glance', 'Action Plan', 'Questionnaires', 'Goals', and 'Notifications'.

Fig. E5 myAirCoach app: Measurements

Various categories of measurements are presented to the participant: 'Health', 'Activity', and 'Environmental'.

Fig. E6 myAirCoach app: Display of the gathered data

Various visualization capabilities of the collected data via the mobile app.

Fig. E7 myAirCoach app: Airica

Virtual assistant based on artificial intelligence and natural language processing.

Fig. E8 myAirCoach inhaler add-on

The inhaler add-on was capable of measuring several critical parameters, such as correct positioning of the inhaler during inhalation as well as the sound of the inhalation procedure.

Fig. E9 myAirCoach app: Inhalation recording

Audio recording and related feedback to the participant

Fig. E10 myAirCoach air quality monitor

The indoor air quality monitor is capable of measuring several indoor parameters such as nitrogen dioxide (NO₂), Sulphur dioxide (SO₂), particulate matter (PM_{2.5} and PM₁₀), humidity, air pressure and temperature.

Fig. E11 m-AQLQ domains

The m-AQLQ divided in the four domain: symptoms, activity, emotions and environment.