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27

28 **Abstract (196 words)**

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30 **Background:** To investigate the performance and patient acceptability of an inhaler electronic
31 monitoring device in a real-world childhood asthma population.

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33 **Methods:** Children 6 to 15 years presenting with asthma to the hospital emergency department and
34 prescribed inhaled corticosteroids were included. Participants were randomized to receive a device
35 with reminder features enabled or disabled for use with their preventer. Device quality control tests
36 were conducted. Questionnaires on device acceptability, utility and ergonomics were completed at
37 six months.

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39 **Results:** A total of 1306 quality control tests were conducted; 84% passed pre-issue and 87% return
40 testing. The most common failure reason was actuation under-recording. Acceptability scores were
41 high, with higher scores in the reminder than non-reminder group (median, 5th-95th percentile: 4.1,
42 3.1-5.0 versus 3.7, 2.3-4.8; $p < 0.001$). Most (>90%) rated the device easy to use. Feedback was
43 positive across five themes: device acceptability, ringtone acceptability, suggestions for
44 improvement, effect on medication use, and effect on asthma control.

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46 **Conclusions:** This study investigates electronic monitoring device performance and acceptability in
47 children using quantitative and qualitative measures. Results indicate satisfactory reliability,
48 although failure rates of 13-16% indicate the importance of quality control. Favorable acceptability
49 ratings support the use of these devices in children.

50 **Keywords:** Acceptability, adherence, asthma, children, devices, electronics

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53 **1.0 Introduction**

54 Adherence to preventive therapy is essential for reducing morbidity in childhood asthma^{1, 2}, yet
55 adherence remains suboptimal³. Electronic monitoring devices (EMDs) are increasingly used to
56 deliver adherence interventions and provide objective adherence data^{4, 5}; but EMDs vary in their
57 accuracy and reliability⁶⁻¹⁰ and there is little data available on patient acceptability^{11, 12}.

58 Implementation of standardized testing is recommended to evaluate the validity of EMD data
59 collected, and measurement of patient-reported EMD acceptability is advised to identify feasibility
60 issues^{13, 14}. However, there is scant research on EMD performance and even fewer studies on patient
61 acceptability in real world populations^{11, 15}.

62 The SmartTrack EMD (Adherium Limited Auckland, New Zealand; Figure 1) is an EMD for pressurized
63 metered dose inhalers (pMDIs). This device has increasingly been used in adherence research^{4, 5, 11} as
64 it has features that are not available on older EMDs, like the Doser¹⁴. These include remote data
65 upload capability, real-time adherence feedback via an on-board screen and multiple customizable
66 functions including customized reminder times and ringtones¹⁴.

67 Whilst this device has been used in several published studies, there is currently little knowledge
68 about its reliability in a real world setting or how patients respond to its use. In one 6-day study,
69 SmartTrack actuation recording accuracy was reported at 99% and ease of use scores were high in
70 adults with asthma¹¹. A recent study investigated the attitudes of seven adolescents towards
71 electronic monitoring after using the SmartTrack for 1 month, which showed generally positive
72 attitudes to adherence monitoring¹². There are however limited data on patient acceptability
73 beyond these small studies, and no published data at all in children. The successful implementation
74 of new health technologies is thought to depend on their acceptability by patients¹⁶, yet at present,
75 little data exists on patient acceptability regarding EMDs^{11, 15}, particularly in children⁶⁻¹⁰.

76 The SmartTrack EMD was recently used in a randomized controlled trial investigating the effects of a
77 reminder EMD on adherence and asthma outcomes in 220 children aged 6 to 15 years presenting
78 with an asthma exacerbation to the regional emergency department (ED) in Auckland, New Zealand
79 ⁴. We found there were significant improvements in adherence and asthma control. The objective of
80 this paper is to assess the performance and patient acceptability of the SmartTrack EMD, when used
81 in this six month trial.

82 **2.0 Patients and methods**

83 **2.1 Patients and trial design**

84 This trial was undertaken in children aged 6 to 15 years, presenting with asthma to the regional ED in
85 Auckland, New Zealand (Australian New Zealand Clinical Trials Registry no. ACTRN12613001353785).
86 The full study design and methods are described in detail elsewhere⁴. All participants with a
87 physician-diagnosis of asthma and prescribed regular, twice-daily inhaled corticosteroids were
88 eligible. Exclusion criteria included diagnosis of chronic lung disease other than asthma, congenital
89 heart disease, residence outside the Auckland area or diagnosis of a severe chronic medical
90 condition leading to impaired immunity or increased morbidity⁴. All participants received the EMD
91 attached to their preventer inhaler; half were randomized to receive the EMD with the reminder
92 functions enabled (reminder group) and half disabled (non-reminder group). Each participant was
93 followed up for six months. Face-to-face visits occurred every two months, where investigators
94 collected the EMD for performance checking and data upload and participants completed
95 questionnaires. Asthma control was assessed using the Asthma Morbidity Score¹⁷ and childhood
96 Asthma Control Test¹⁸. Written informed consent was provided by the child's parent or guardian,
97 and written assent obtained from children.

98 **2.2 The electronic adherence monitoring device**

99 Each SmartTrack EMD had an on-board reminder function which could be enabled or disabled by the
100 investigators. When enabled, the EMD delivered twice-daily reminders for missed doses (Figure 1).
101 Reminder times were set by investigators prior to each visit, as per participant preference. The
102 reminder sounded until the correct dose was taken or for a maximum of fifteen minutes, and did not
103 sound if the correct dose was taken in the six hours preceding the set reminder time. One of
104 fourteen different ringtones played each time in a cyclical pattern. The EMD recorded the date and
105 time of each actuation, ringtone initiation and sound, and pMDI or battery removal and insertion;
106 this was stored until data upload. Adherence data was determined from these EMD records. The
107 EMD battery compartment and pMDI entry door were secured using security screws to minimize
108 participant tampering.

109 Each participant was issued with an EMD at the first visit and shown how to use the device. The EMD
110 was replaced at every visit. Participants were told that the study was investigating the effect of a
111 reminder inhaler on asthma; the adherence monitoring function was not disclosed, as per
112 established ethical guidelines¹⁹, to avoid interference with usual behavior.

113 **2.3 EMD quality control testing**

114 All devices were checked according to a standardized quality control (QC) procedure at two time
115 points during the study: prior to issue to participants ('pre-issue' QC testing) and after return from
116 participants ('return' QC testing) as described below and in the Supplemental Table S1 (online)¹⁴.
117 Tests were carried out by one of three trained investigators.

118 *QC testing pass threshold*

119 Devices "passed" testing if all maneuvers were recorded with 100% event and time accuracy. At
120 baseline an allowance of ± 2 minutes was made for internal clock time drift, and ± 15 minutes after
121 the two-monthly visits¹⁵. Reasons for QC test failure were documented and classified into categories.

122 Where more than one reason occurred, the primary reason for failure was reported. Affected
123 devices were returned to the manufacturer for analysis, repair and data retrieval.

124 *'Pre-issue' QC testing*

125 QC tests were conducted in both reminder and non-reminder modes on each device. Pre-issue QC
126 tests included checks for physical damage and functional and recording accuracy of actuations and
127 reminders (Supplemental Table S1 (online)). Actuation recording accuracy was checked by actuating
128 different numbers of puffs at different times of the day to mimic correct, over-, under- and zero
129 dosing. Reminders were checked for accuracy of reminder timing, duration and response to under-
130 and correct dosing. Investigators carried the EMD in pockets or bags in between active testing to
131 mimic real life use.

132 *'Return' QC testing*

133 Return QC tests, similar to pre-issue tests (Supplemental Table S1 (online)), were carried out
134 immediately after collecting the device from the participant to retain pre-return device conditions
135 for accuracy checking of the device. Devices collected from the reminder group underwent a full
136 return QC test; devices from the non-reminder group underwent a shorter return test, which
137 omitted the reminder tests, as reminder testing was irrelevant.

138 **2.4 EMD acceptability and ringtone rating score**

139 Children completed a questionnaire about device acceptability at study end. The 7-item
140 questionnaire was scored on a 5-point semantic differential scale (1=strongly disagree, 5=strongly
141 agree) which asked about topics such as ease of use, usefulness for medication reminding, perceived
142 effects on asthma control and device size. Item 7 (using my new asthma inhaler in front of other
143 people is embarrassing) was negatively worded. Participants using a reminder EMD completed an
144 8th question asking how much they liked the reminder sounds and extra questions on ringtone

145 preference (14 ringtones were rated on a 4-point Likert scale (0 = very bad, 3 = very good)), device
146 size (too big, just right, too small) and whether the device was easy to hold (yes, no). All
147 questionnaires were completed by the child without assistance from the parent or caregiver. Where
148 assistance was needed with interpretation and completion of the questionnaires, this was provided
149 by the researcher. Children and caregivers could also provide written feedback about the device via
150 a free-text comments field at the end of the paper questionnaire or through verbal feedback to the
151 investigators either at or between visits via telephone. Feedback was optional. All written and verbal
152 feedback were coded into themes by AC. The emergent themes were reviewed by AC and JMF; any
153 discrepancies in the themes assigned were resolved by discussion. Ethics approval was obtained
154 from the New Zealand Northern Y Regional Ethics Committee (NTY/08/12/116) and District Health
155 Boards.

156 **2.5 Statistical analysis**

157 Descriptive statistics were calculated for patient demographics and acceptability scores. The mean
158 number of faults per participant and acceptability scores were compared in reminder and non-
159 reminder patients using the Mann-Whitney U test. To determine whether there was any association
160 between adherence and asthma control with acceptability scores for each item, univariate analyses
161 were conducted using a general linear model with the variables as covariates. The Friedman test was
162 used to compare ringtone ratings. P-values of less than 0.05 indicated statistical significance.
163 Analyses were undertaken on the intention to treat population using IBM SPSS Statistics (version
164 22)(IBM Corp, Armonk, NY, USA).

165 **3.0 Results**

166 As described previously⁴, of 656 patients initially identified as potentially eligible, 253 were ineligible
167 on further assessment, 41 could not be contacted, 57 declined participation, 82 had already been
168 assessed for eligibility and 3 excluded for other reasons. The remaining 220 participants were

169 enrolled and 110 participants randomized to each group – the reminder EMD group versus the non-
170 reminder group. The participant flow diagram is shown in Figure 2, with baseline characteristics
171 summarized in Table 1.

172 **3.1 EMD performance**

173 There were four categories of device failure (Table 2): data recording, reminder, battery or data
174 upload faults. Pre-issue QC tests were conducted on 628 devices, of which 527 (84%) passed. The
175 majority of failures were due to actuation recording inaccuracies (67%), followed by reminder faults
176 (17%).

177 During the study, 694 devices were issued (an average of three devices per participant; a new device
178 at baseline, 2- and 4-month visits); 16 (2%) were not returned at study completion. Return QC
179 testing was carried out on the remaining 678 devices, of which 591 (87%) passed. Of the 87 (13%)
180 that failed, actuation recording inaccuracies accounted for the majority (95%) of failures. Physical
181 damage was observed in four EMDs. The mean \pm SD number of device faults per participant did not
182 differ between the two groups (intervention: 0.45 ± 0.79 versus control: 0.34 ± 0.62 ; $p=0.33$).

183 **3.2 EMD acceptability, adherence and asthma control**

184 Ninety eight per cent (108/110) of participants in the reminder group and 95% (104/110) in the non-
185 reminder group completed the acceptability questionnaire. Median scores in both groups were high
186 for most acceptability questions (medians 4 or higher) indicating that the majority were highly
187 satisfied with the EMD (Table 3).

188 A number of individual items were scored significantly higher in the reminder group including: ease
189 of remembering (Reminder: median 5.0 (25th, 75th percentile: 4.0, 5.0) vs. non-reminder 4.0 (3.0,
190 4.25); $p<0.001$) and knowing better when to take their asthma medication (Reminder: median 5.0
191 (4.0, 5.0) vs. non-reminder 4.0 (3.0, 4.0); $p<0.001$). Patients who received reminders also reported

192 feeling more in control of their asthma (Reminder: 4.0 (4.0, 5.0) vs. non-reminder: 4.0 (3.0, 5.0),
193 $p=0.001$). These improvements in *perceived* medication taking and *perceived* asthma control in the
194 reminder group corresponded with *actual* improvements in objective measures of asthma control
195 and adherence; the details of these results are reported elsewhere⁴. This is supported by the
196 significant relationship seen between the statements “Knowing when to take my asthma medication
197 is easy” and adherence ($p<0.0005$), and “I feel more in control of my asthma now” and the Asthma
198 Morbidity Score and childhood Asthma Control Test (Appendices A1, A2 and A3).

199 **3.3 Ringtone ratings**

200 Of the 110 reminder EMD users, 104 (95%) completed the ringtone ratings questionnaire. There was
201 a significant difference in the ratings of 14 different ringtones ($\chi^2(13) = 185, P < 0.001$). The highest
202 ratings were for popular culture ringtones like “The Simpsons”, which had a median rating of 3 (25th-
203 75th percentile: 2-3). The lowest median ratings were for animal sound ringtones like “Donkey”,
204 which received a rating of 2 (25th-75th percentile: 0.25-2).

205 **3.4 Device ergonomics**

206 One hundred of the 110 (91%) reminder EMD users completed the question on device handling, and
207 99 (90%) completed the question on device size. Ninety four percent (94/100) agreed the device was
208 easy to hold; 6% (6/100) disagreed. For device size, 81% (80/99) rated the device “just right”, 16%
209 (16/99) “too big” and 3% (3/99) “too small”.

210 **3.5 Feedback about the EMD**

211 Verbal and written comments about the device were provided by 44 individuals (24 children, 20
212 caregivers; 41 unique participant IDs). Of these individuals, 22 provided written, 21 verbal and 1
213 both written and verbal comments. Feedback was coded into five themes: EMD acceptability,

214 ringtone acceptability, suggestions for EMD improvement, effect of EMD on medication use and
215 effect of EMD on asthma control (Table 4).

216 Some children reported finding the reminders intrusive due to ringtone type, volume, or reminder
217 time but most responded favorably, describing reminders as helpful for medication taking. Many
218 caregivers perceived improvements in their child's asthma control as a result of EMD use.

219 **4.0 Discussion**

220 With an increase in EMD use in research, it is important to determine: a) if EMDs are feasible and
221 practical for use in children, b) if EMDs can perform reliably in children over an extended period, and
222 c) what unique factors need to be considered in this age group. We believe this is the first study to
223 report on both EMD performance and quantitative and qualitative measures of patient acceptability
224 of an EMD when used by children. The discussion below will focus on these two aspects –
225 performance and acceptability – and the limitations of our study findings. Although the study
226 specifically investigated the SmartTrack EMD in children presenting to the ED with asthma (i.e. a
227 population at high-risk of non-adherence), these methods and results are likely applicable to other
228 EMDs as well as other age groups when assessing an EMD for patient use.

229 **4.1 EMD performance**

230 Our QC failure rates were lower than previously reported in a SmartTrack validation study among
231 adults (20–25%)¹¹; but aligned with rates reported for other more established EMDs, such as the
232 Doser (0-21%)^{9, 20, 21}, MDIlog / Chronolog (10-53%)^{8, 9, 22, 23} and Smartinhaler (0-20%)^{15, 24, 25}, and were
233 within the maximum 10-20% failure rates considered feasible for research settings¹¹. In the present
234 study the SmartTrack EMD was used for longer and included more participants than the adult
235 validation study¹¹, thus likely providing more representative performance data. Further, the devices
236 were used in children recruited from ED, providing the first acceptability data in a population whose

237 adherence and asthma control was poor^{26,27}, and where the device was challenged by real-life
238 conditions, such as rough handling. In such populations, adherence monitoring may provide the
239 most benefit, thus suggesting our performance results are generalizable to the population where
240 EMDs are most needed⁴.

241 **4.2 Limitations – EMD performance**

242 Although the failure rate in children aligns with that of other available EMDs when used in adults, it
243 remains a small but important percentage, which may need to be lower to encourage device
244 implementation in clinical settings. Our requirement for 100% accuracy on all tested functions was
245 exacting and may not have been necessary or realistic. At the start of the trial in 2010, the
246 SmartTrack was a new device which lacked reported performance data; shorter tests may become
247 more appropriate as reliable EMD performance data become available^{4,5}.

248 **4.3 EMD acceptability, adherence, and asthma control**

249 After six months of use, participants reported good acceptability for the EMD, including being willing
250 to continue use (in both groups) and rating the reminder EMD favorably for medication reminding
251 and knowing when to take medication. The reminder group also reported feeling significantly more
252 in control of their asthma than participants without reminders. Improvements in perceived asthma
253 control was reported both quantitatively via the EMD acceptability scale and qualitatively from
254 participant feedback. The improvements in perceived control corresponds to data we have
255 previously published⁴ on clinical asthma control in the same cohort; change from baseline in asthma
256 control test scores at 6 months was significantly greater in the reminder group (BL: 18.8 (SD 4.5),
257 6M: 22.7 (3.7)), compared with the non-reminder group (BL: 18.8 (4.2), 6M: 21.4 (4.2), $p < 0.0001$).
258 The improvements in perceived control thus mirrored the improvements seen from objective
259 measures. Of note, the EMD acceptability statements around asthma medication taking and asthma
260 control corresponded with objective measures of adherence and asthma control respectively

261 (Appendices A1, A2 and A3). The present results therefore suggest that a reminder EMD not only
262 improves clinical asthma control, but it may correspondingly improve *perceived* asthma control
263 (Table 3). This is important and signals further research, especially since greater perceived control of
264 asthma has been associated with improved health status and decreased future risk of severe
265 exacerbations requiring emergency healthcare utilization²⁸.

266 *Ringtone ratings and device ergonomics*

267 Participants rated the ringtone options favorably, with a preference for popular culture ringtones,
268 such as “The Simpsons”, and a lower preference for loud, abrupt or harsh ringtones, and animal
269 sounds. Most (94%) rated the EMD as easy to hold and only a small proportion (16%) reported EMD
270 size as “too big”. The large size of the SmartTrack EMD has been noted previously¹¹, however EMDs
271 are likely to become more compact with time. Indeed the re-branded version of the SmartTrack
272 EMD (SmartTouch) appears to have addressed this by utilizing a smaller and softer casing¹⁴. EMD
273 designers should consider these user preferences and ergonomic factors carefully when developing
274 devices, particularly for use in children.

275 **4.4 Strengths and Limitations – EMD acceptability**

276 Previous research on EMD performance has focused predominantly on accuracy and reliability^{8, 13, 15,}
277 ^{22, 24, 29} and lacks data on user acceptability, which is key to sustained patient use¹⁶. In the present
278 study, we created a 7-item acceptability questionnaire which explored a variety of criteria, including
279 attitudes to device use in public, responses to device features and ergonomic factors such as size
280 and ease of handling. The questionnaire was designed such that it can be administered relatively
281 quickly and easily to children. Whilst this questionnaire was designed for the SmartTrack EMD and
282 was answered by children, we specifically included questions generalizable to other EMDs and other
283 age groups¹⁴ such as assessing satisfaction with continued use, effects on medication management
284 and attitudes to use in public (Table 3). The ratings in the questionnaire were skewed, as is common

285 to satisfaction rating scales³⁰⁻³², and while distributional skew did not prevent the finding of
286 statistical differences between the reminder and non-reminder groups, the magnitude of the
287 difference between groups may have been underestimated. Further, like the questionnaires used in
288 the small acceptability studies carried out previously in adults and adolescents^{11, 12}, our acceptability
289 questionnaire was not validated. Young children can have difficulty comprehending the language
290 used in questionnaires, and older children may refuse to complete questionnaires or provide
291 inaccurate answers³³. Although we report a high questionnaire completion rate (>95%), we cannot
292 be certain that the questionnaire responses of younger children were not influenced by
293 comprehension difficulties, though researchers assisted with comprehension where appropriate.
294 Further validation testing of our questionnaire is recommended in a future acceptability study in
295 children.

296 **5.0 Conclusions**

297 This study reports on both EMD performance and patient acceptability in children. Device
298 performance was consistent with that of other EMDs, though there remains a small but important
299 failure rate which needs to be addressed prior to use in a clinical setting. This study reinforces the
300 practical approach and resources needed for QC testing and its key role for enhancing the integrity
301 of adherence data. Using a combination of quantitative and open-text qualitative methods to
302 explore patient acceptability, we found that the SmartTrack EMD was highly acceptable, highlighting
303 the feasibility of its use in children. EMD use also positively affected attitudes toward adherence and
304 perceptions of asthma control. Further research combining EMD reliability and acceptability
305 assessments, including the influence of EMD use on perceptions of disease control, is recommended
306 to ensure a wide and successful uptake of EMDs in research and clinical settings, and to increase our
307 understanding of the role of EMDs in adherence interventions.

308 **Key issues:**

- 309 - Electronic monitoring devices (EMDs) are increasingly used in adherence research and
310 clinical practice
- 311 - There is little information in the literature about the performance and acceptability of EMD
312 use in children
- 313 - This study reports on the performance and use of EMDs in children
- 314 - EMDS were found to be highly acceptable in children
- 315 - There was a small but significant failure rate of EMDs which will need to be addressed prior
316 to implementation in routine practice
- 317 - The study highlights the potential for use of EMDs in children
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320 **6.0 References**

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405 **Figure legends**

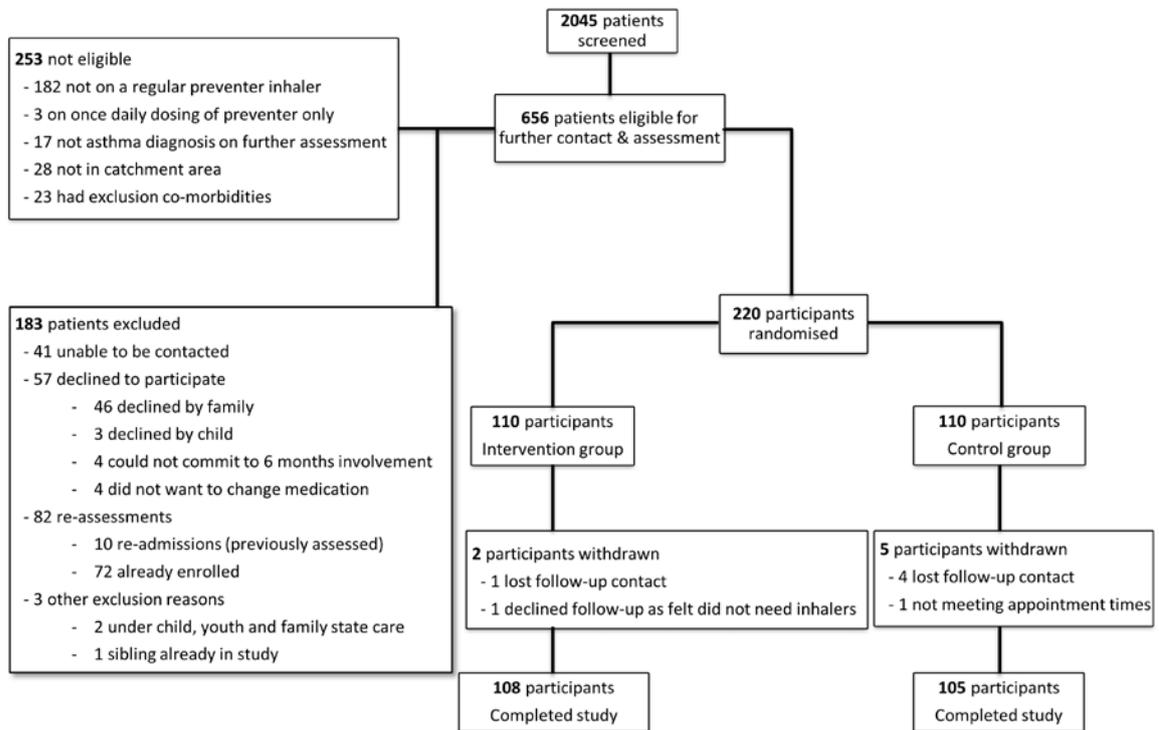
406 **Figure 1: Smart Track electronic monitoring device (image supplied by Adherium Limited,**

407 **Auckland, New Zealand) – front view with device attached to MDI**



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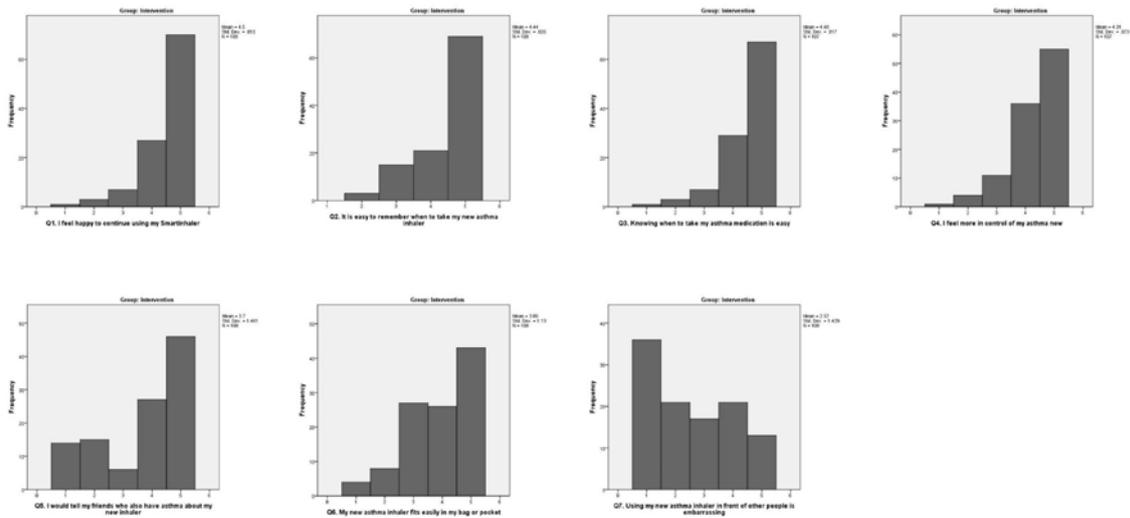
415 **Figure 2. Participant flow diagram for inclusion of participants in the clinical trial**



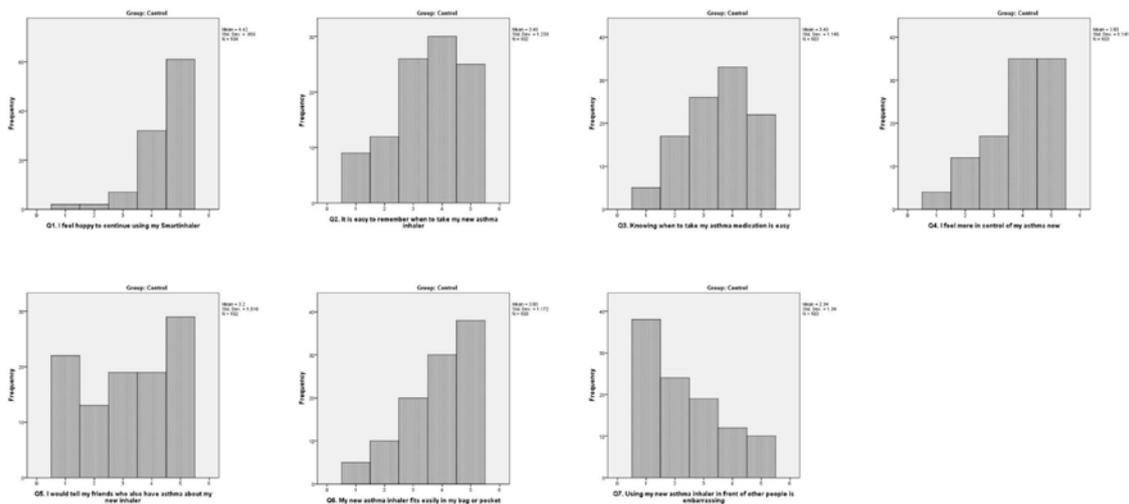
416

417 **Figures 3a and b – Histograms depicting distribution of participant responses to acceptability**

418 **questionnaire items 1 to 7**



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