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Adapting a club-based medication delivery strategy to a hypertension context: The CLUBMEDS Study in Nigeria

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3 **46 ABSTRACT**
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6 **47 INTRODUCTION:** The prevalence of hypertension in sub-Saharan Africa (SSA) is among
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54 **METHODS AND ANALYSIS:** The CLUBMEDS study will include a formative (pre-
55 implementation) qualitative evaluation, a pilot study and a process (post-implementation)
56 qualitative evaluation. At the formative stages, focus group discussions with patient groups and
57 in-depth interviews with healthcare providers, managers and key decision makers will be
58 conducted to understand the feasibility, barriers and facilitators, opportunities and challenges
59 for the successful implementation of the CLUBMEDS strategy. The CLUBMEDS pilot study
60 will be implemented in two primary healthcare facilities, one urban and one rural, in Southeast
61 Nigeria. Each adherence club, which consists of a group of 10-15 patients with hypertension
62 under the leadership of a role-model patient, serves as a support group to encourage and
63 facilitate adherence, BP self-monitoring and medication delivery on a monthly basis. A process
64 evaluation will be conducted at the end of the pilot study to evaluate the acceptability and
65 engagement with the CLUBMEDS strategy. To date, 103 patients were recruited and grouped
66 into 9 clubs, in which patients will be followed-up for six months.

67 **ETHICS AND DISSEMINATION:** The study was approved by the University of Abuja
68 Teaching Hospital and the Federal Teaching Hospital Abakaliki Human Research Ethics
69 Committees and all patients provided informed consent. Our findings will provide preliminary

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3 70 data on the potential effectiveness and acceptance of this strategy in a hypertension context.
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6 71 Study findings will be disseminated via scientific forums.
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12 73 **ABSTRACT WORD COUNT: 299 (max. 300)**
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18 75 **KEYWORDS:** Medication adherence, peer-support groups, adherence clubs, hypertension,
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89 STRENGTHS AND LIMITATIONS OF THIS STUDY

- 90 • Hypertension prevalence in sub-Saharan Africa (SSA) is among the world's highest;
91 however, access to anti-hypertensive treatment is limited by significant health system,
92 geographical and financial barriers.
- 93 • Alternative models of care using community peer-support groups are a promising
94 strategy to overcome these barriers to hypertension control and reach those patients
95 who are not captured in regular healthcare settings.
- 96 • Adherence clubs, which consists of groups of 10-15 patients with hypertension under
97 the leadership of a role-model patient, might be a promising strategy, serving as a
98 support group to encourage and facilitate adherence, blood pressure self-monitoring
99 and medication delivery.
- 100 • The CLUBMEDS study, which will include a formative (pre-implementation)
101 qualitative evaluation, a pilot study and a process (post-implementation) qualitative
102 evaluation, aims to evaluate the feasibility and impact of adherence clubs to improve
103 hypertension control in Nigeria.
- 104 • This study is a pilot study and, therefore, it is limited by its small sample size and short-
105 term follow-up; however, the study findings will provide preliminary data on the
106 potential effectiveness and acceptance of this strategy in a hypertension context.

107

108 INTRODUCTION

109 The Burden of Hypertension in Sub-Saharan Africa and Nigeria

110 Hypertension is the second leading risk factor for lost disability-adjusted life-years (DALYs)
111 in men and the leading risk factor in women globally.[1] Despite the global effort to mitigate
112 the impact of hypertension worldwide, it remains a major public health threat, accounting for
113 10.5 million deaths in 2016.[1] A recent meta-analysis estimated the prevalence of
114 hypertension to be 28.5% in high-income countries (HICs) and 31.5% in low and middle-
115 income countries (LMICs), accounting for 349 million and 1.04 billion people living with
116 hypertension, respectively, in 2010.[2] Proportions of awareness, treatment and control of
117 hypertension are lower in LMICs when compared to HICs. In 2010, the estimated awareness,
118 treatment and control rates for hypertension were 37.9%, 29.0% and 7.7%, respectively, in
119 LMICs; while in HICs they were estimated to be 67.0%, 55.6% and 28.4%, respectively.[2]

120

121 The prevalence of hypertension in sub-Saharan Africa (SSA) is among the world's highest,
122 having been reported to vary between 15% and 70% among SSA countries, with an average of
123 30%.[3] SSA had the highest prevalence of hypertension in women in 2010.[2] Approximately
124 128.6 million people in SSA were living with hypertension in 2010, having increased from
125 50.4 million in 2000.[2] This steady increase has been attributed mainly due to increased life
126 expectancy, urbanisation and globalization, and consequent changes in lifestyle behaviours,
127 such as smoking, reduced physical activity, and unhealthy diet.[4] Furthermore, the impact of
128 hypertension is worse in SSA countries. It is known that mortality and morbidity rates
129 associated with hypertension and its complications, such as ischaemic heart disease, stroke and
130 heart failure, are higher in SSA when compared to other regions of the world.[5] These
131 complications are worsened by the low rates of hypertension awareness and treatment in SSA.

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3 132 Rates of awareness (27%), treatment (18%) and control (7%) of hypertension in SSA are some
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5 133 of the lowest in the world.[3] In addition, many SSA countries struggle to appropriately tackle
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7 134 hypertension, as they face a double burden of communicable and chronic diseases, and often
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9 135 healthcare spending on communicable diseases is prioritised, resulting in hypertension-related
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11 136 healthcare spending not being enough to cover the costs of basic diagnostic equipment, health
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13 137 workers training and treatment supplies.[4, 5].
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21 139 Nigeria is the most populous country in Africa with an estimated population of 193 million in
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23 140 2016.[6] Like other SSA countries, the prevalence of hypertension in Nigeria is high. A recent
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25 141 review found that the pooled prevalence of hypertension in Nigeria was 22.5%, varying
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27 142 between 8.0% and 46.4%, depending on the target population, type of measurement and
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29 143 hypertension definition.[7] In Nigeria, hypertension awareness (14.2% to 30%), treatment
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31 144 (18.6 to 21.0%) and control (5.0% to 17.5%) are similar to other SSA countries.[7]
32
33 145 Hypertension has also been associated with high rates of stroke, ischaemic heart disease, heart
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35 146 failure and chronic kidney disease in Nigeria[7]. Therefore, hypertension is a major public
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37 147 health challenge in this country.
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45 149 **Barriers to Blood Pressure Control**

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48 150 There are three major categories of barriers to control of hypertension: 1) patient-related, 2)
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50 151 provider-related, and 3) healthcare system-related.[8, 9] Patient-related barriers are well-
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52 152 known and include low health literacy, beliefs and attitudes about hypertension and its
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54 153 treatment;[8, 9] depression, anxiety and stress;[8, 10] lack of motivation and social support;[8]
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56 154 and medication side effects and costs.[9] Some of the provider-related barriers include lack of
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3 155 knowledge about treatment guidelines, lack of trust in clinical guidelines, clinical inertia on
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5 156 initiating or up-titrating the treatment, and communication issues, such as lack of
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7 157 encouragement for medication adherence and blood pressure (BP) control.[8, 9] In addition,
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9 158 there are other barriers at the level of healthcare systems, which include long distance to the
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11 159 healthcare facility, long waiting time for consultations, insufficient diagnostic equipment,
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13 160 inadequate numbers of health workers trained to manage patients with hypertension, and
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15 161 inadequate or absent health insurance coverage in many LMICs.[5]
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23 163 In Nigeria, a 2014 study evaluated patient-related barriers to control of hypertension and found
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25 164 a few key factors that could explain poor hypertension control. This study found a poor
26
27 165 knowledge of consequences of inadequate BP control, forgetfulness in taking BP medications
28
29 166 and non-affordability of medications.[11] Another study from Nigeria reported that the main
30
31 167 barriers to medication adherence and BP control included healthcare system-related barriers,
32
33 168 such as inconvenient clinic operating hours, long waiting times and under-dispensing of
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35 169 prescribed medications, when due to the lack of availability of anti-hypertensive medications
36
37 170 the pharmacists dispense a smaller quantity of pills than needed by the patients.[12] Patient-
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39 171 related barriers were also reported, such as the lack of knowledge that regular medication use
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41 172 is needed and interruption of the anti-hypertensive treatment due to side effects or
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43 173 cultural/faith-motivated reasons.[12] Moreover, some of the above-mentioned barriers often
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45 174 interfere with the patients' daily life, for example, due to inconvenient clinic operating hours,
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47 175 long distances and long waiting times, the patients usually need to take a day off from work to
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49 176 attend the clinic. The consequence of missing a day of work might be that patients would have
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51 177 less money to purchase the anti-hypertensive medications. To overcome some of these barriers,
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53 178 alternative models of care, in which there is a shift of the provision of care and treatment from
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55 179 the healthcare facilities to the community are needed.
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181 Community-Based Models of Care

182 The term communitisation of healthcare has been previously used to describe the shift in how
183 healthcare is delivered, where the patients, the communities and the healthcare system share
184 the responsibility for finding solutions to healthcare problems and challenges.[13] Peer support
185 groups are an example of this concept of communitisation of care. Peer support groups consist
186 of groups of patients with the same health condition, in which the patients support each other
187 and share the challenges, and often the solutions, of living with that specific chronic health
188 condition. Previous studies have shown that peer support groups improve patient experience,
189 adherence, health outcomes and service use among patients with different health conditions,
190 mainly mental illness and HIV/AIDS.[13]

191

192 In the HIV/AIDS context, different types of peer support groups have been studied and shown
193 to be effective. One of these types of peer support groups are the so-called adherence clubs. In
194 these adherence clubs, lay counsellors, who act as the club facilitators, dispense medication to
195 stable patients in a community setting.[14-16] The lay counsellors also measure weight,
196 conduct symptom-based general assessments and provide peer support to encourage
197 medication adherence.[17] A few studies in patients with HIV/AIDS in South Africa have
198 shown that this club-based strategy improved adherence, reduced virological rebound and
199 improved retention in care. [15, 18-20]

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201 The adherence clubs were proven effective in the HIV/AIDS setting and it has the potential to
202 be translated to other chronic diseases, such as hypertension. However, to date, this club-based

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3 203 strategy has not been evaluated for other chronic disease conditions. Therefore, the
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5 204 CLUBMEDS study aims to evaluate a community club-based strategy to deliver anti-
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8 205 hypertensive medication to patients with hypertension in Southeast Nigeria.
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14 207 **METHODS AND ANALYSIS**

17 208 **The CLUBMEDS Study**

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20 209 The CLUBMEDS study aims to evaluate the feasibility and impact of adherence clubs to
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22 210 improve hypertension control in Nigeria. For a community-based model/strategy to work, it is
23
24 211 essential to involve the patients, their relatives and the whole community in the planning and
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26 212 implementation of such strategy. Before implementing any community-based strategy, it is
27
28 213 important to understand patients' preferences, the barriers and facilitators from various
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30 214 stakeholders' perspectives, including patients, healthcare providers and the health system
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32 215 managers. Therefore, this feasibility evaluation will provide valuable insights for future
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34 216 implementation of a community club-based medication delivery strategy in a larger scale and
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36 217 will guide important adaptations to the model depending on the context it is being implemented.
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45 219 The CLUBMEDS study will include a formative (pre-implementation) qualitative evaluation,
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47 220 a pilot study and a process (post-implementation) qualitative evaluation.
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53 222 **Patient and Public involvement statement**

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56 223 It is important to acknowledge that patients will be involved in the development of this study.
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225 **Formative qualitative evaluation**

226 As part of the CLUBMEDS study, a qualitative evaluation will be done at the formative stage
227 of the strategy. Focus group discussions with patient groups and in-depth interviews with
228 healthcare providers, managers and key decision makers will be conducted to understand the
229 feasibility, barriers and facilitators, opportunities and challenges for the successful
230 implementation of the CLUBMEDS strategy. This qualitative evaluation will also help build
231 ownership of the CLUBMEDS strategy among the stakeholders. We will explore three main
232 conceptual areas; 1) current understanding of hypertension and the health risks associated with
233 it, 2) the challenges faced in accessing and adhering to medications by those who are using
234 anti-hypertensive medications, and 3) the perceived value and acceptability of future
235 implementation of the CLUBMEDS strategy.

237 **The CLUBMEDS pilot study**

238 The CLUBMEDS pilot study will be implemented in two primary healthcare facilities, one
239 urban and one rural, in Southeast Nigeria. The urban site is located at Abakaliki, the capital
240 city of Ebonyi State. According to the 2006 census, the population in Abakaliki city was
241 79,280, while in the Abakaliki Local Government Area was 149,683.[21, 22] To date, there is
242 no published data on the prevalence of hypertension in Abakaliki, however, a study in a nearby
243 urban city of Enugu with similar population characteristics reported an overall prevalence of
244 hypertension of 42%. The rural site is located at Awkuzu, a town in Oyi Local Government
245 Area of Anambra State. According to the 2006 census, population of Oyi Local Government
246 Area was 168,201, [23] however there is no published data on the Awkuzu's population.
247 According to the unpublished report of the Removing the Mask on Hypertension (REMAH)
248 project, prevalence, treatment and control of hypertension in Awkuzu is 18.61%, 8.23% and
249 1.98%, respectively.

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4
5 251 The structure of the CLUBMEDS pilot study will mimic the structure used in the HIV/AIDS
6 adherence clubs. The CLUBMEDS adherence clubs will consist of one role-model patient, who
7
8 252 will act as the club facilitator, and between 10 to 15 patients with hypertension, who will be
9
10 253 called club members. The adherence clubs will meet on a monthly basis for six months.
11
12 254 Between three to five adherence clubs will be formed in each primary healthcare facility,
13
14 255 aiming to recruit a total of at least 100 patients (Figure 1). In each primary healthcare facility,
15
16 256 community health extension workers (CHEWs) and nurses will be the point of contact for any
17
18 257 clinical support to the adherence clubs.
19
20 258
21
22 259

23 24 25 26 260 Recruitment and training

27
28 261 Research assistants working on the CLUBMEDS study in each primary healthcare facility will
29
30 262 recruit patients with hypertension to participate in the CLUBMEDS strategy. All patients will
31
32 263 be required to provide informed consent to participate in the study. After obtaining informed
33
34 264 consent, the research assistant will perform a baseline assessment, in which information on
35
36 265 demographics, hypertension history, comorbidities, lifestyle risk factors, anti-hypertensive
37
38 266 medications being taken, and medication adherence will be collected. In addition, BP
39
40 267 measurements will be performed using an automated BP monitor. The research assistants will
41
42 268 then identify and select patients that are eligible to be the role-mode patients. To be eligible to
43
44 269 be a role-model patient, the selected patients will have to meet the following criteria:

- 45
46
47 270 1) Be considered adherent to the anti-hypertensive treatment, if they:
- 48
49 271 • have collected the anti-hypertensive medication every month in the last six
 - 50
51 272 months, and
 - 52
53 273 • have attended the primary healthcare facility at least twice in the last six months;
- 54
55 274 2) Have at least secondary school completion;
- 56
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3 275 3) Agree to take the responsibility of acting as the club facilitator.
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7
8 277 After identifying and selecting the role-model patients, the research assistants will provide
9
10 278 training on BP monitoring, management of hypertension and how the CLUBMEDS strategy
11
12 279 will work to both the role-model patients and the facility CHEWs. CHEWs will participate in
13
14 280 a 3-day training program, while role-model patients will receive a simplified and tailored 1-
15
16
17 281 day training program. The training will include:

- 18
19 282
- 20 • Basic information on hypertension:
 - 21 283 ▪ Epidemiology, causes, related risk factors, diagnosis and management of
 - 22 284 hypertension;
 - 23
24 285 ▪ Information on non-pharmacologic management of hypertension;
 - 25
26 286 ▪ Information on the importance of adherence to anti-hypertensive medications;
 - 27
28 287 ▪ Information on the importance of regular BP checks.
 - 29
30
31 288
 - 32 • Training on:
 - 33 289 ▪ How to measure BP appropriately with an automated BP monitor;
 - 34
35 290 ▪ How to identify alert signs, e.g. uncontrolled and complications of high BP;
 - 36
37 291 ▪ Management of the adherence clubs, including how to register the patients,
 - 38
39 292 record data in the register and distribute the medications to the patients (only to
 - 40
41 293 role-model patients).
 - 42
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48
49 295 Finally, the research assistants will help the patients to form the CLUBMEDS adherence clubs
50
51 296 by assigning one role-model patient and around 10 to 15 patients with hypertension, the club
52
53 297 members, to an adherence club based on their domiciliary proximity. Once the adherence clubs
54
55 298 are formed, the patients take responsibility on the overall running of the clubs.
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3 300 CLUBMEDS monthly sessions
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6 301 The CLUBMEDS adherence clubs will meet on a monthly basis in a local community centre.
7

8 302 The role-model patient and the club members will decide which day and time the clubs will
9

10
11 303 meet on a regular basis, e.g. every last Sunday of the month at 6:00pm.
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17 305 The role-model patients will act as the club facilitators, being responsible for preparing and
18

19 306 running the club sessions, including the following tasks:
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21

22 307 • Preparing for the club session, including ensuring that the anti-hypertensive medication
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24 308 refills are ordered from the pharmacist at the healthcare facility and ready for pick-up
25

26 309 before the club session;
27
28

29 310 • Registering club members by writing the club members' names in the CLUBMEDS
30

31 311 monthly session register when they arrive to the club session;
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33

34 312 • Measuring the club members' BP using an automated BP monitor;
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37 313 • Delivering the anti-hypertensive medications to each club member;
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39

40 314 • Recording information in the CLUBMEDS monthly session register, including: the BP
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42 315 measurements, the quantity of pills returned by the club members, if any, and the
43

44 316 quantity of pills provided to each club member in the current club session;
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46

47 317 • Supporting/educating the club members about adherence;
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50 318 • Identifying any symptoms and alert signs in the club members;
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53 319 • Referring club members back to the primary healthcare facility to be evaluated by a
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55 320 CHEW or nurse, if symptom/alert signs are present or, if the club member is due to a
56

57 321 regular 6 months check-up at the facility;
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60 322 • After the club session, returning any uncollected medications to the pharmacy and
61

62 323 following-up with club members who missed the club session.
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324

325 The facility CHEWs and nurses will be the point of contact for the role-model patients and club
326 members in the primary healthcare facilities to support to the overall conduct of the adherence
327 clubs; however, they will not be present in the CLUBMEDS monthly sessions. The facility
328 CHEWs and nurses will be still responsible for the clinical management of the patients
329 participating in the CLUBMEDS study by:

- 330 • Ensuring the six-monthly scripting of club members;
- 331 • Scheduling regular return visits to the facility for club members every six months;
- 332 • Up-titrating or changing the anti-hypertensive medications;
- 333 • Evaluating club members with symptoms/alert signs who are referred to the facility by
334 the role-model patients;
- 335 • Supporting the role-model patients in any club-related issues, if necessary.

336

337 The pharmacist or pharmacist assistant at the facility will be responsible for pre-packing the
338 anti-hypertensive medication refills for the adherence clubs to be collected by the role model
339 patients before every CLUBMEDS monthly session. There will be no regular physician
340 involvement in the CLUBMEDS strategy due to shortages of physicians working in the primary
341 healthcare facilities involved in the study. In these facilities, non-physicians (CHEWs and
342 nurses) are the ones responsible for seeing and handling the patients' health issues.

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344 CLUBMEDS outcomes

345 The CLUBMEDS strategy will be tested for six months and the outcome variables to be
346 evaluated during this pilot study are presented in Box 1. At six months, the role-model patients

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3 347 and club members will be re-assessed by the CLUBMEDS research assistants. Data on
4
5 348 medication adherence, BP, hospitalisations due to cardiovascular clinical events and the anti-
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7 349 hypertensive medications being taken by the participants will be collected by the research
8
9 350 assistants. Medication adherence will be assessed using a visual analogue scale, information
10
11 351 on the number of pills missed in the last seven days and pill count. Three BP measurements
12
13 352 will be conducted using an automated BP monitor (Omron model 705IT). The first BP
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15 353 measurement will be discarded and the mean value of the last two measurements will be
16
17 354 calculated. Data on the club attendance, BP measurements and medication adherence collected
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19 355 during the club sessions will be also evaluated.
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27 **Box 1: CLUBMEDS primary and secondary outcomes**

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29 **Primary**

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32 • Medication adherence – Visual analog scale
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35 **Secondary**

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38 • Medication adherence – Number of pills missed in the last 7 days and pill count
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40 • Blood pressure – Resting, sitting automated digital recording, mean of last two readings
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42 • Hospital admissions due to cardiovascular clinical events – Self-report
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44 • Attendance to club sessions – CLUBMEDS monthly session register
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47 • Acceptability and engagement with the CLUBMEDS strategy (As part of the process
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49 qualitative evaluation)
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56 359 **Process qualitative evaluation**
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3 360 A process evaluation will be conducted at the end of the pilot study (post-implementation stage)
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5 361 to evaluate the acceptability and engagement with the CLUBMEDS strategy. Focus group
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7 362 discussions with club members and in-depth interviews with the role-model patients, CHEWs,
8
9 363 nurses, pharmacists, and any other healthcare providers involved in the CLUBMEDS study
10
11 364 will be conducted to understand the strengths and weaknesses of the strategy, what worked and
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13 365 what did not work, how can the strategy be adapted and improved according to any challenges
14
15 366 identified in this pilot study that might preclude the future successful implementation of the
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17 367 CLUBMEDS strategy.
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24 369 **CLUBMEDS Progress to Date**

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26 370 The recruitment to the CLUBMEDS strategy started in March 2018. Two focus groups (18
27
28 371 male and 20 female participants) and five in-depth interviews were successfully conducted,
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30 372 and more are being planned in both the urban and rural sites as part of the formative qualitative
31
32 373 evaluation. This qualitative data is currently being analysed and the findings will be published
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34 374 in a separate paper.
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41 376 To date, 104 patients were recruited to participate in the CLUBMEDS pilot study, being 82 in
42
43 377 the urban site and 22 in the rural site. Nine role-model patients were identified, selected and
44
45 378 trained to run the adherence clubs in both sites. Seven adherence clubs were formed in the
46
47 379 urban site with between 10 and 13 club members in each club, while two adherence clubs were
48
49 380 formed in the rural site with 10 and 13 club members in each club. At the baseline assessment,
50
51 381 the recruited CLUBMEDS participants had a mean age of 56.8 years (SD 10.7), 73 (70%) were
52
53 382 women, and a mean BP of 146.7/86.9 mmHg (SD 20.1/11.2). The majority of participants
54
55 383 reported taking only one (49.0%) or two (47.1%) anti-hypertensive medications at the baseline
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57 384 assessment, while only 3.8% reported taking three classes of anti-hypertensive medications.
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3 385 The median medication adherence percentage of anti-hypertensive medications taken by the
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5 386 participants in the past month was 44.5% (IQR 30) measured by the visual analogue scale. The
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7 387 CLUBMEDS monthly sessions are currently being held successfully.
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13 14 390 **ETHICS AND DISSEMINATION**

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16
17 391 The findings of this study will be disseminated via scientific forums including peer-reviewed
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19 392 publications and presentations at international and national conferences. The study design and
20
21 393 conduct is being overseen by a steering committee (authors), a group of Emerging Leaders
22
23 394 from the World Heart Federation. This committee has expertise in large-scale clinical trials,
24
25 395 qualitative research and clinical CVD management. This study will adhere to the Declaration
26
27 396 of Helsinki, a statement of ethical principles for medical research involving human subjects.
28
29 397 The study was approved by the University of Abuja Teaching Hospital and the Federal
30
31 398 Teaching Hospital Abakaliki Human Research Ethics Committees and all patients provided
32
33 399 informed consent.
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39 400

40 401 **DISCUSSION**

41
42 402 Hypertension is a major public health issue worldwide and even more so in LMICs, such as
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44 403 Nigeria. The current healthcare facility-based model of care has failed to provide appropriate
45
46 404 care to ensure adequate BP control in patients with hypertension. Alternative models of care
47
48 405 based on shared responsibility between patients, communities and the healthcare system might
49
50 406 be the way forward. The CLUBMEDS study is one of the first studies evaluating a community
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52 407 club-based strategy to deliver anti-hypertensive medication to patients with hypertension in
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54 408 Nigeria, adapting a strategy that was shown to be effective in HIV/AIDS to the hypertension
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56 409 context.
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6 411 In the HIV/AIDS context, a variety of innovative strategies to increase community engagement
7
8 412 in the care and anti-retroviral therapy (ART) delivery have been piloted and studied in southern
9
10 413 Africa in the last decade.[14, 16, 24, 25] Community-based models of ART delivery aims to
11
12 414 improve retention in care, by separating drug delivery from clinical visits. From the patient
13
14 415 perspective, the main advantages of these strategies are the reduction of travel costs and time
15
16 416 spent in frequent clinic visits, and peer support encouragement at the community level.[14, 16]
17
18 417 From the healthcare system's perspective, the major advantages are the reduction of staff
19
20 418 workload, keeping the clinical staff focussed on clinical problems, and the encouragement of
21
22 419 patient autonomy.[14, 16] One of these strategies that has been previously implemented and
23
24 420 evaluated is the community-based ART adherence clubs, including facility-based and
25
26 421 community-based adherence clubs.[14, 16]
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35 423 Similar to the CLUBMEDS strategy, in the ART adherence club community-based medication
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37 424 delivery strategy, lay counsellors dispensed the medications to stable patients in a community
38
39 425 setting, either in patients' home or at community venues.[14-16] The lay counsellors, who
40
41 426 acted as the club facilitators, were also responsible for measuring the patients' weight,
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43 427 conducting symptom-based general assessments and providing peer support to encourage
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45 428 medication adherence.[17] These ART adherence clubs, which had between 15-30 patients,
46
47 429 met regularly and were supported by a facility nurse.[17]
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55 431 An evaluation of the club-based strategy for HIV/AIDS in South Africa showed that, less than
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57 432 0.1% (9/2133) patients died and 0.3% (53/2133) were referred back to the facility due to
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3 433 clinical complications over 18 months.[18] In another study in South Africa, 12% more patients
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5 434 remained in care and were 67% less likely to experience virological rebound in the club-based
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8 435 strategy compared to clinic-based care.[15, 26] This club-based strategy has also been shown
9
10 436 to reduce costs and have fewer barriers to ongoing access to care, including shorter waiting
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12 437 times, higher acceptability of services and fewer missed clinic appointments.[27]
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15 438

17
18 439 An important finding from these studies was that for the club-based strategy to be successful it
19
20 440 was essential that the medications, in this case the ART, were pre-packaged and labelled for
21
22 441 each patient at the facility, and that the club facilitator collected and transported the packs to
23
24 442 the meeting venue. Also, it was important that patients reporting any symptoms or adverse
25
26 443 effects, such as weight loss in the HIV/AIDS context, were referred back to the facility to be
27
28 444 assessed by a nurse, and that all club participants saw a facility nurse at least once a year for
29
30 445 their regular clinical check-up.
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38 447 If also shown to be effective and acceptable to the patients and other stakeholders, the
39
40 448 CLUBMEDS strategy has the potential to change the current hypertension scenario, especially
41
42 449 in resource-limited settings like many SSA countries, including Nigeria. The CLUBMEDS
43
44 450 strategy has the potential of delivering a better care to patients with hypertension, by involving
45
46 451 them, their relatives and their communities in their healthcare. With this engagement, we aim
47
48 452 to improve the patients' knowledge about hypertension, encourage medication adherence and
49
50 453 facilitate medication delivering, bringing the medications closer to the patients.
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58 455 **CONCLUSION**
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3 456 With the growing burden of hypertension in Nigeria and other LMICs, a change in the current
4
5 457 model of hypertension management and treatment from the healthcare facility to community,
6
7 458 is imperative. If we are to achieve the ‘25 x 25’ World Heart Federation and World Health
8
9 459 Organisation target of reducing premature cardiovascular disease mortality by 25% by 2025
10
11 460 worldwide, we need to accelerate our efforts in bringing anti-hypertensive treatment closer to
12
13 461 the population and ensure that at least 50% of eligible people are receiving medications to
14
15 462 prevent heart attacks and strokes. A club-based strategy, which was shown to be effective and
16
17 463 acceptable in the HIV/AIDS context, can similarly improve provision of care and treatment to
18
19 464 hypertensive patients in resource-limited areas in LMICs. The CLUBMEDS study aims to
20
21 465 evaluate a similar club-based strategy in patients with hypertension in Nigeria, where
22
23 466 hypertension awareness, treatment and control remains suboptimal. The CLUBMEDS pilot
24
25 467 study together with the formative and process qualitative evaluations will provide important
26
27 468 preliminary data on the potential implementation of this approach in the hypertension context.
28
29 469 If this strategy is shown to be feasible and acceptable, future studies may test the effectiveness
30
31 470 of this strategy to improve BP control and longer-term medication adherence in LMICs, such
32
33 471 as Nigeria. The CLUBMEDS findings will add to the body of evidence supporting adherence
34
35 472 clubs as a way to overcome barriers to optimal treatment adherence.
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474 **DECLARATIONS**

475 **Statement**

476 The Corresponding Author has the right to grant on behalf of all authors and does grant on
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56 481 **Ethics approval**
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9 482 The study was approved by the University of Abuja Teaching Hospital and the Federal
10 483 Teaching Hospital Abakaliki Human Research Ethics Committees and all patients provided
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12 484 informed consent.
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18
1920 486 **Competing interests**
21

22 487 The authors declare no potential conflicts of interest with respect to the research, authorship
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4142 494 **Authors' contributors**
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23 604 **Figure 1: A model of club-based medication delivery strategy in hypertension context**
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25 605 **from CLUBMEDS Study being implemented in Nigeria**

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28 606 Note: P refers to a patient or club member.
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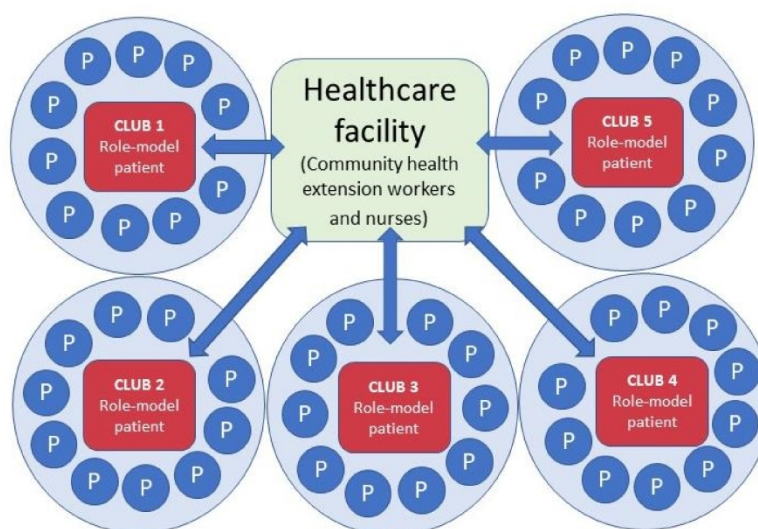


Figure 1: A model of club-based medication delivery strategy in hypertension context from CLUBMEDS Study being implemented in Nigeria

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Adapting a club-based medication delivery strategy to a hypertension context: The CLUBMEDS Study in Nigeria

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3 1 **TITLE**
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6 2 Adapting a club-based medication delivery strategy to a hypertension context: The
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8 3 CLUBMEDS Study in Nigeria
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40 **WORD COUNT: 4054 (max. 4000) – Excluding title page, abstract, strengths and**
41 **limitations, tables, figures, declarations and references.**

42 **BOXES: 1**

43 **FIGURES: 1**

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2
3 46 **ABSTRACT**
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6 47 **INTRODUCTION:** The prevalence of hypertension in sub-Saharan Africa (SSA) is among
7
8 48 the world's highest; however, awareness, treatment and control of hypertension in this region
9
10 49 are sub-optimal. Among other barriers, the overburdened healthcare system poses a great
11
12 50 challenge for hypertension control. Community peer-support groups are an alternative and
13
14 51 promising strategy to improve adherence and blood pressure (BP) control. The CLUBMEDS
15
16 52 study aims to evaluate the feasibility and impact of adherence clubs to improve hypertension
17
18 53 control in Nigeria.
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23 54 **METHODS AND ANALYSIS:** The CLUBMEDS study will include a formative (pre-
24
25 55 implementation) qualitative evaluation, a pilot study and a process (post-implementation)
26
27 56 qualitative evaluation. At the formative stages, focus group discussions with patient groups and
28
29 57 in-depth interviews with healthcare providers, managers and key decision makers will be
30
31 58 conducted to understand the feasibility, barriers and facilitators, opportunities and challenges
32
33 59 for the successful implementation of the CLUBMEDS strategy. The CLUBMEDS pilot study
34
35 60 will be implemented in two primary healthcare facilities, one urban and one rural, in Southeast
36
37 61 Nigeria. Each adherence club, which consists of a group of 10-15 patients with hypertension
38
39 62 under the leadership of a role-model patient, serves as a support group to encourage and
40
41 63 facilitate adherence, BP self-monitoring and medication delivery on a monthly basis. A process
42
43 64 evaluation will be conducted at the end of the pilot study to evaluate the acceptability and
44
45 65 engagement with the CLUBMEDS strategy. To date, 104 patients were recruited and grouped
46
47 66 into 9 clubs, in which patients will be followed-up for six months.
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54 67 **ETHICS AND DISSEMINATION:** The study was approved by the University of Abuja
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56 68 Teaching Hospital and the Federal Teaching Hospital Abakaliki Human Research Ethics
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58 69 Committees and all patients provided informed consent. Our findings will provide preliminary
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3 70 data on the potential effectiveness and acceptance of this strategy in a hypertension context.
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6 71 Study findings will be disseminated via scientific forums.
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12 73 **ABSTRACT WORD COUNT: 299 (max. 300)**
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18 75 **KEYWORDS:** Medication adherence, peer-support groups, adherence clubs, hypertension,
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20 76 anti-hypertensives
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89 STRENGTHS AND LIMITATIONS OF THIS STUDY

- 90 • Hypertension prevalence in sub-Saharan Africa (SSA) is among the world's highest;
91 however, access to anti-hypertensive treatment is limited by significant health system,
92 geographical and financial barriers.
- 93 • Alternative models of care using community peer-support groups are a promising
94 strategy to overcome these barriers to hypertension control and reach those patients
95 who are not captured in regular healthcare settings.
- 96 • Adherence clubs, which consists of groups of 10-15 patients with hypertension under
97 the leadership of a role-model patient, might be a promising strategy, serving as a
98 support group to encourage and facilitate adherence, blood pressure self-monitoring
99 and medication delivery.
- 100 • The CLUBMEDS study, which will include a formative (pre-implementation)
101 qualitative evaluation, a pilot study and a process (post-implementation) qualitative
102 evaluation, aims to evaluate the feasibility and impact of adherence clubs to improve
103 hypertension control in Nigeria.
- 104 • This study is a pilot study and, therefore, it is limited by its small sample size and short-
105 term follow-up; however, the study findings will provide preliminary data on the
106 potential effectiveness and acceptance of this strategy in a hypertension context.

107

108 INTRODUCTION

109 The Burden of Hypertension in Sub-Saharan Africa and Nigeria

110 Hypertension is the second leading risk factor for lost disability-adjusted life-years (DALYs)
111 in men and the leading risk factor in women globally.[1] Despite the global effort to mitigate
112 the impact of hypertension worldwide, it remains a major public health threat, accounting for
113 10.5 million deaths in 2016.[1] The estimated prevalence of hypertension was 28.5% in high-
114 income countries (HICs) and 31.5% in low and middle-income countries (LMICs), accounting
115 for 349 million and 1.04 billion people living with hypertension, respectively, in 2010.[2] In
116 addition, the estimated awareness, treatment and control rates for hypertension were 37.9%,
117 29.0% and 7.7%, respectively, in LMICs; while in HICs they were estimated to be 67.0%,
118 55.6% and 28.4%, respectively.[2]

119

120 The prevalence of hypertension in sub-Saharan Africa (SSA) is among the world's highest,
121 having been reported to vary between 15% and 70% among SSA countries, with an average of
122 30%.[3] Approximately 128.6 million people in SSA were living with hypertension in 2010,
123 having increased from 50.4 million in 2000.[2] Furthermore, it is known that mortality and
124 morbidity rates associated with hypertension and its complications, such as ischaemic heart
125 disease, stroke and heart failure, are higher in SSA when compared to other regions of the
126 world.[4] This high prevalence of complications is worsened by the low rates of hypertension
127 awareness (27%), treatment (18%) and control (7%) in SSA.[3] In addition, many SSA
128 countries struggle to appropriately tackle hypertension, as they face a double burden of
129 communicable and chronic diseases, and often healthcare spending on communicable diseases
130 is prioritised, resulting in hypertension-related healthcare spending not being enough to cover
131 the costs of basic diagnostic equipment, health workers training and treatment supplies.[4, 5]

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3 132 Nigeria is the most populous country in Africa with an estimated population of 193 million in
4
5 133 2016.[6] Like other SSA countries, the prevalence and complication rates of hypertension in
6
7 134 Nigeria are high, while hypertension awareness, treatment and control are low. The prevalence
8
9 135 of hypertension in Nigeria was estimated to be 22.5%, while hypertension awareness was
10
11 136 estimated to be between 14.2% and 30%, treatment between 18.6 and 21.0% and control
12
13 137 between 5.0% and 17.5%).[7] Therefore, hypertension is a major public health challenge in
14
15 138 this country.
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23 140 **Barriers to Blood Pressure Control**

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26 141 There are three major categories of barriers to control of hypertension: 1) patient-related, 2)
27
28 142 provider-related, and 3) healthcare system-related.[8, 9] In Nigeria, a 2014 study evaluated
29
30 143 patient-related barriers and found that poor knowledge of consequences of inadequate BP
31
32 144 control, forgetfulness in taking BP medications and non-affordability of medications were
33
34 145 associated with poor hypertension control.[10] Another study from Nigeria reported that the
35
36 146 main barriers to medication adherence and BP control included healthcare system-related
37
38 147 barriers, such as inconvenient clinic operating hours, long waiting times and under-dispensing
39
40 148 of prescribed medications, when due to the lack of availability of anti-hypertensive medications
41
42 149 the pharmacists dispense a smaller quantity of pills than needed by the patients.[11] Patient-
43
44 150 related barriers were also reported, such as the lack of knowledge that regular medication use
45
46 151 is needed and interruption of the anti-hypertensive treatment due to side effects or
47
48 152 cultural/faith-motivated reasons.[11] To overcome some of these barriers, alternative models
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50 153 of care, in which there is a shift of the provision of care and treatment from the healthcare
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52 154 facilities to the community are needed.
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156 **Community-Based Models of Care**

157 The term communitisation of healthcare has been previously used to describe the shift in how
158 healthcare is delivered, in which patients, communities and healthcare systems share the
159 responsibility for finding solutions to healthcare problems and challenges.[12] Peer support
160 groups are an example of this concept of communitisation of care. Peer support groups consist
161 of groups of patients with the same health condition, in which the patients support each other
162 and share the challenges, and often the solutions, of living with that specific chronic health
163 condition. Previous studies have shown that peer support groups improve patient experience,
164 adherence, health outcomes and service use among patients with different health conditions,
165 mainly mental illness and HIV/AIDS.[12]

166

167 In the HIV/AIDS context, different types of peer support groups have been studied and shown
168 to be effective. One of these types of peer support groups are the so-called adherence clubs. In
169 these adherence clubs, lay counsellors, who act as the club facilitators, dispense medication to
170 stable patients in a community setting.[13-15] The lay counsellors also measure weight,
171 conduct symptom-based general assessments and provide peer support to encourage
172 medication adherence.[16] A few studies in patients with HIV/AIDS in South Africa have
173 shown that this club-based strategy improved adherence, reduced virological rebound and
174 improved retention in care.[14, 17-19]

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176 The adherence clubs were proven effective in the HIV/AIDS setting and it has the potential to
177 be translated to other chronic diseases, such as hypertension. However, to date, this club-based
178 strategy has not been evaluated in other chronic disease conditions. Therefore, the

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3 179 CLUBMEDS study aims to evaluate a community club-based strategy to deliver anti-
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5 180 hypertensive medication to patients with hypertension in Southeast Nigeria.
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11 182 **METHODS AND ANALYSIS**

13 183 **The CLUBMEDS Study**

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18 184 The CLUBMEDS study aims to evaluate the feasibility and impact of adherence clubs to
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20 185 improve hypertension control in Nigeria. For a community-based model/strategy to work, it is
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22 186 essential to involve the patients, their relatives and the whole community in the planning and
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24 187 implementation of such strategy. Before implementing any community-based strategy, it is
25
26 188 important to understand patients' preferences, the barriers and facilitators from various
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28 189 stakeholders' perspectives, including patients, healthcare providers and the health system
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30 190 managers. Therefore, this feasibility evaluation will provide valuable insights for future
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32 191 implementation of a community club-based medication delivery strategy in a larger scale and
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34 192 will guide important adaptations to the model depending on the context it is being implemented.
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43 194 The CLUBMEDS study will include a formative (pre-implementation) qualitative evaluation,
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45 195 a pilot study and a process (post-implementation) qualitative evaluation.
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51 197 **Patient and Public involvement statement**

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54 198 It is important to acknowledge that patients will be involved in the development of this study.
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60 200 **Formative qualitative evaluation**

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3 201 As part of the CLUBMEDS study, a qualitative evaluation will be done at the formative stage
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5 202 of the strategy. Focus group discussions with patient groups and in-depth interviews with
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7 203 healthcare providers, managers and key decision makers will be conducted to understand the
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9 204 feasibility, barriers and facilitators, opportunities and challenges for the successful
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11 205 implementation of the CLUBMEDS strategy. This qualitative evaluation will also help build
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13 206 ownership of the CLUBMEDS strategy among the stakeholders. We will explore three main
14
15 207 conceptual areas; 1) current understanding of hypertension and the health risks associated with
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17 208 it, 2) the challenges faced in accessing and adhering to medications by those who are using
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19 209 anti-hypertensive medications, and 3) the perceived value and acceptability of future
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21 210 implementation of the CLUBMEDS strategy.
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29 212 **The CLUBMEDS pilot study**

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32 213 The CLUBMEDS pilot study will be implemented in two primary healthcare facilities, one
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34 214 urban and one rural, in Southeast Nigeria. The urban site is located at Abakaliki, the capital
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36 215 city of Ebonyi State. According to the 2006 census, the population in Abakaliki city was
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38 216 79,280, while in the Abakaliki Local Government Area was 149,683.[20, 21] To date, there is
39
40 217 no published data on the prevalence of hypertension in Abakaliki, however, a study in a nearby
41
42 218 urban city of Enugu with similar population characteristics reported an overall prevalence of
43
44 219 hypertension of 42%. The rural site is located at Awkuzu, a town in Oyi Local Government
45
46 220 Area of Anambra State. According to the 2006 census, population of Oyi Local Government
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48 221 Area was 168,201, [22] however there is no published data on the Awkuzu's population.
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50 222 According to the unpublished report of the Removing the Mask on Hypertension (REMAH)
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52 223 project, prevalence, treatment and control of hypertension in Awkuzu is 18.61%, 8.23% and
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54 224 1.98%, respectively.
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3 226 The structure of the CLUBMEDS pilot study will mimic the structure used in the HIV/AIDS
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5 227 adherence clubs. The CLUBMEDS adherence clubs will consist of one role-model patient, who
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8 228 will act as the club facilitator, and between 10 to 15 male and female patients with hypertension,
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10 229 who will be called club members. The adherence clubs will meet on a monthly basis for six
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12 230 months. Between three to five adherence clubs will be formed in each primary healthcare
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14 231 facility. As this is a pilot study evaluating the feasibility of the CLUBMEDS strategy, we are
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16 232 aiming to recruit a convenient sample of 100 patients (Figure 1). In each primary healthcare
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18 233 facility, community health extension workers (CHEWs) and nurses will be the point of contact
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20 234 for any clinical support to the adherence clubs.
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26 236 Recruitment and training

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28 237 Research nurses working on the CLUBMEDS study will recruit hypertensive patients in each
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30 238 primary healthcare facility to participate in the CLUBMEDS strategy. To be eligible to
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32 239 participate in the study, patients will have to have a confirmed diagnosis of hypertension and
33
34 240 be indicated for treatment with anti-hypertensive medications, irrespective of their level of
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36 241 adherence at baseline. All patients will be required to provide informed consent to participate
37
38 242 in the study. After obtaining informed consent, the research nurse will perform a baseline
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40 243 assessment, in which information on demographics, hypertension history, comorbidities,
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42 244 lifestyle risk factors, anti-hypertensive medications being taken, and medication adherence will
43
44 245 be collected. In addition, BP measurements will be performed using an automated BP monitor.
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46 246 Among the enrolled patients, the research nurses will then identify and select patients that are
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48 247 eligible to be the role-mode patients. To be eligible to be a role-model patient, the selected
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50 248 patients will have to meet the following criteria:
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56 249 1) Be considered adherent to the anti-hypertensive treatment, if they:
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3 250 • have collected the anti-hypertensive medication every month in the last six
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5 251 months, and
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8 252 • have attended the primary healthcare facility at least twice in the last six months;
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10 253 2) Have at least secondary school completion;
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12 254 3) Agree to take the responsibility of acting as the club facilitator.
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17 256 After identifying and selecting the role-model patients, the research nurses will provide training
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19 257 on BP monitoring, management of hypertension and how the CLUBMEDS strategy will work
20
21 258 to both the role-model patients and the facility CHEWs. CHEWs will participate in a 3-day
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23 259 training program, while role-model patients will receive a simplified and tailored 1-day training
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25
26 260 program. The training will include:

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29 261 • Basic information on hypertension:
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31 262 ▪ Epidemiology, causes, related risk factors, diagnosis and management of
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33 263 hypertension;
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35 264 ▪ Information on non-pharmacologic management of hypertension;
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37 265 ▪ Information on the importance of adherence to anti-hypertensive medications;
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39 266 ▪ Information on the importance of regular BP checks.
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42 267 • Training on:
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44 268 ▪ How to measure BP appropriately with an automated BP monitor;
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46 269 ▪ How to identify alert signs, e.g. uncontrolled and complications of high BP;
47
48 270 ▪ Management of the adherence clubs, including how to register the patients,
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50 271 record data in the register and distribute the medications to the patients (only to
51
52 272 role-model patients).
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3 274 Finally, the research nurses will help the patients to form the CLUBMEDS adherence clubs by
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5 275 assigning one role-model patient and around 10 to 15 patients with hypertension, the club
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7 276 members, to an adherence club based on their domiciliary proximity. Once the adherence clubs
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10 277 are formed, the patients take responsibility on the overall running of the clubs.
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13
14 279 CLUBMEDS monthly sessions

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18 280 The CLUBMEDS adherence clubs will meet on a monthly basis in a local community centre.

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20 281 The role-model patient and the club members will decide which day and time the clubs will

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22 282 meet on a regular basis, e.g. every last Sunday of the month at 6:00pm. The monthly adherence

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24 283 club meeting will be open for club members relatives or friends who wish to attend and support

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26 284 the club members in adhering to their anti-hypertensive treatment.
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33 286 The role-model patients will act as the club facilitators, being responsible for preparing and

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35 287 running the club sessions, including the following tasks:
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39 288 • Preparing for the club session, which includes ensuring that the anti-hypertensive
40
41 289 medication refills are ordered from the pharmacist at the healthcare facility and ready
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43 290 for pick-up before the club session;

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46 291 • Registering club members by writing the club members' names in the CLUBMEDS
47
48 292 monthly session register when they arrive to the club session;

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50 293 • Measuring the club members' BP using an automated BP monitor;

51
52 294 • Delivering the anti-hypertensive medications to each club member;

53
54
55 295 • Recording information in the CLUBMEDS monthly session register, including: the BP
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57 296 measurements, the quantity of pills returned by the club members, if any, and the
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59 297 quantity of pills provided to each club member in the current club session;

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3 298 • Supporting/educating the club members about adherence;
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6 299 • Identifying any symptoms and alert signs for complications of uncontrolled
7
8 300 hypertension in the club members, e.g. extremely high levels of BP, severe headache,
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10 301 dizziness, blurred vision, nausea/vomiting, nosebleeds, chest pain/shortness of breath,
11
12 302 etc;
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14
15 303 • Referring club members back to the primary healthcare facility to be evaluated by a
16
17 304 CHEW or nurse, if symptom/alert signs are present or, if the club member is due to a
18
19 305 regular 6 months check-up at the facility;
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21
22 306 • After the club session, returning any uncollected medications to the pharmacy and
23
24 307 following-up with club members who missed the club session.

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26
27 308 Given that their responsibilities are quite extensive, the role-model patients will receive some
28
29 309 incentives to be the club facilitators. The role-model patients will be able to keep the automated
30
31 310 BP monitor after the study completion and will receive financial support to purchase BP
32
33 311 monitor batteries and for transportation to the facility.

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37 312 The facility CHEWs and nurses will be the point of contact for the role-model patients and club
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39 313 members in the primary healthcare facilities to support to the overall conduct of the adherence
40
41 314 clubs and to help resolve any adherence-related issues that role-model patients might not be
42
43 315 able to address during the club meetings. However, the CHEWs and nurses will not be present
44
45 316 in the CLUBMEDS monthly sessions. The facility CHEWs and nurses will be still responsible
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47 317 for the clinical management of the patients participating in the CLUBMEDS study by:

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52 318 • Ensuring the six-monthly scripting for club members;
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54 319 • Scheduling regular return visits to the facility for club members every six months;
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56
57 320 • Up-titrating or changing the anti-hypertensive medications;
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3 321 • Evaluating club members with symptoms/alert signs who are referred to the facility by
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5 322 the role-model patients and, if necessary, referring them to the hospital for further
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7 323 evaluation, the Federal Teaching Hospital Abakiliki for club members from the urban
8
9 324 facility and the Chukwuemeka Odumegwu Ojukwu University Teaching Hospital
10
11 325 Awka for club members from the rural facility;
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14
15 326 • Supporting the role-model patients in any club-related issues, if necessary.
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18 327

21 328 Due to lack of pharmacists and pharmacist assistants at the facilities, the facility nurses and the
22
23 329 CHEWs will be responsible for pre-packing the anti-hypertensive medication refills for the
24
25 330 adherence clubs to be collected by the role-model patients before every CLUBMEDS monthly
26
27 331 session. There will be no regular physician involvement in the CLUBMEDS strategy due to
28
29 332 shortages of physicians working in the primary healthcare facilities involved in the study. In
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31 333 these facilities, non-physicians (CHEWs and nurses) are the ones responsible for seeing and
32
33 334 handling the patients' health issues.
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41 336 Data collection and outcomes

44 337 The CLUBMEDS strategy will be tested for six months and the outcome variables to be
45
46 338 evaluated during this pilot study are presented in Box 1. At six months, the role-model patients
47
48 339 and club members will be re-assessed by the CLUBMEDS research nurses. Data on medication
49
50 340 adherence, BP, hospitalisations due to cardiovascular clinical events and the anti-hypertensive
51
52 341 medications being taken by the participants will be collected by the research nurses. Medication
53
54 342 adherence will be assessed using a visual analogue scale, information on the number of pills
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56 343 missed in the last seven days and pill count. Three BP measurements will be conducted using
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3 344 an automated BP monitor (Omron model 705IT). The first BP measurement will be discarded
4
5 345 and the mean value of the last two measurements will be calculated. Data on the club
6
7 346 attendance, BP measurements and medication adherence collected during the club sessions will
8
9 347 be also evaluated. All data will be entered by the research nurses in a secure password-protected
10
11 348 electronic database (REDCap).
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18 **Box 1: CLUBMEDS primary and secondary outcomes**

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20 **Primary**

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23 • Medication adherence – Visual analog scale
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26 **Secondary**

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28 • Medication adherence – Number of pills missed in the last 7 days and pill count
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30 • Blood pressure – Resting, sitting automated digital recording, mean of last two readings
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32 • Hospital admissions due to cardiovascular clinical events – Self-report
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34 • Attendance to club sessions – CLUBMEDS monthly session register
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36 • Acceptability and engagement with the CLUBMEDS strategy (As part of the process
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38 qualitative evaluation)
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45 351 **Statistical analysis**

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47 352 Baseline data will be presented as means and standard deviations (SD) or medians and
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49 353 interquartile ranges (IQR) for continuous variables, and as frequencies and percentages for
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51 354 categorical variables. A pre-post analysis will be done for the analyses of the study outcomes.
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53 355 Continuous variables will be analysed using t-tests and categorical variables using χ^2 tests as
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55 356 appropriate. Mann-Whitney U tests will be used if data are not normally distributed.
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3 357 To further understand important determinants of medication adherence in our study population,
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5 358 we will perform linear regression analyses using the visual analog scale as a continuous
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7 359 variable. We will also perform logistic regression analyses using a defined cut-off on the visual
8
9 360 analog scale (e.g. adherence $\geq 80\%$). The study team is well aware of the small sample size of
10
11 361 the pilot study and therefore, variable selection for these models will be parsimonious and the
12
13 362 results will only be hypothesis-generating.
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19 364 **Process qualitative evaluation**

21 365 A process evaluation will be conducted at the end of the pilot study (post-implementation stage)
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23 366 to evaluate the acceptability and engagement with the CLUBMEDS strategy. Focus group
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25 367 discussions with club members and in-depth interviews with the role-model patients, CHEWs,
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27 368 nurses, pharmacists, and any other healthcare providers involved in the CLUBMEDS study
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29 369 will be conducted to understand the strengths and weaknesses of the strategy, what worked and
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31 370 what did not work, how can the strategy be adapted and improved according to any challenges
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33 371 identified in this pilot study that might preclude the future successful implementation of the
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35 372 CLUBMEDS strategy.
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42 374 **CLUBMEDS Progress to Date**

44 375 The recruitment to the CLUBMEDS strategy started in March 2018. Two focus groups (18
45
46 376 male and 20 female participants) and five in-depth interviews were successfully conducted,
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48 377 and more are being planned in both the urban and rural sites as part of the formative qualitative
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50 378 evaluation. This qualitative data is currently being analysed and the findings will be published
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52 379 in a separate paper.
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3 381 To date, 104 patients were recruited to participate in the CLUBMEDS pilot study between
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5 382 March and September 2018, being 82 in the urban site and 22 in the rural site. Nine role-model
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7 383 patients were identified, selected and trained to run the adherence clubs in both sites. Seven
8
9 384 adherence clubs were formed in the urban site with between 10 and 13 club members in each
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11 385 club, while two adherence clubs were formed in the rural site with 10 and 13 club members in
12
13 386 each club. At the baseline assessment, the recruited CLUBMEDS participants had a mean age
14
15 387 of 56.8 years (SD 10.7), 73 (70%) were women, and a mean BP of 146.7/86.9 mmHg (SD
16
17 388 20.1/11.2). The majority of participants reported taking only one (49.0%) or two (47.1%) anti-
18
19 389 hypertensive medications at the baseline assessment, while only 3.8% reported taking three
20
21 390 classes of anti-hypertensive medications. The median medication adherence percentage of anti-
22
23 391 hypertensive medications taken by the participants in the past month was 44.5% (IQR 30)
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25 392 measured by the visual analogue scale. The CLUBMEDS monthly sessions are currently being
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27 393 held successfully.
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35 396 **ETHICS AND DISSEMINATION**

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40 397 The findings of this study will be disseminated via scientific forums including peer-reviewed
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42 398 publications and presentations at international and national conferences. The study design and
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44 399 conduct are being overseen by a steering committee (authors), a group of Emerging Leaders
45
46 400 from the World Heart Federation. This committee has expertise in large-scale clinical trials,
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48 401 qualitative research and clinical CVD management. This study will adhere to the Declaration
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50 402 of Helsinki, a statement of ethical principles for medical research involving human subjects.
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52 403 The study was approved by the University of Abuja Teaching Hospital and the Federal
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54 404 Teaching Hospital Abakaliki Human Research Ethics Committees and all patients provided
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56 405 informed consent.
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407 **DISCUSSION**

408 Hypertension is a major public health issue worldwide and even more so in LMICs, such as
409 Nigeria. The current healthcare facility-based model of care has failed to provide appropriate
410 care to ensure adequate BP control in patients with hypertension. Alternative models of care
411 based on shared responsibility between patients, communities and the healthcare system might
412 be the way forward. The CLUBMEDS study is one of the first studies evaluating a community
413 club-based strategy to deliver anti-hypertensive medication to patients with hypertension in
414 Nigeria, adapting a strategy that was shown to be effective in HIV/AIDS to the hypertension
415 context.

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417 In the HIV/AIDS context, a variety of innovative strategies to increase community engagement
418 in the care and anti-retroviral therapy (ART) delivery have been piloted and studied in southern
419 Africa in the last decade.[13, 15, 23, 24] Community-based models of ART delivery aims to
420 improve retention in care, by separating drug delivery from clinical visits. From the patient
421 perspective, the main advantages of these strategies are the reduction of travel costs and time
422 spent in frequent clinic visits, and peer support encouragement at the community level.[13, 15]
423 From the healthcare system's perspective, the major advantages are the reduction of staff
424 workload, keeping the clinical staff focussed on clinical problems, and the encouragement of
425 patient autonomy.[13, 15] One of these strategies that has been previously implemented and
426 evaluated is the community-based ART adherence clubs, including facility-based and
427 community-based adherence clubs.[13, 15]

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3 429 Similar to the CLUBMEDS strategy, in the ART adherence club community-based medication
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5 430 delivery strategy, lay counsellors dispensed the medications to stable patients in a community
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7 431 setting, either in patients' home or at community venues.[13-15] The lay counsellors, who
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9 432 acted as the club facilitators, were also responsible for measuring the patients' weight,
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11 433 conducting symptom-based general assessments and providing peer support to encourage
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13 434 medication adherence.[16] These ART adherence clubs, which had between 15-30 patients,
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15 435 met regularly and were supported by a facility nurse.[16] An evaluation of the club-based
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17 436 strategy for HIV/AIDS in South Africa showed that, less than 0.1% (9/2133) patients died and
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19 437 0.3% (53/2133) were referred back to the facility due to clinical complications over 18
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21 438 months.[17] In another study in South Africa, 12% more patients remained in care and were
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23 439 67% less likely to experience virological rebound in the club-based strategy compared to clinic-
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25 440 based care.[14, 25] This club-based strategy has also been shown to reduce costs and have
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27 441 fewer barriers to ongoing access to care, including shorter waiting times, higher acceptability
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29 442 of services and fewer missed clinic appointments.[26]

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39 444 An important finding from these studies was that for the club-based strategy to be successful it
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41 445 was essential that the medications, in this case the ART, were pre-packaged and labelled for
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43 446 each patient at the facility, and that the club facilitator collected and transported the packs to
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45 447 the meeting venue. Also, it was important that patients reporting any symptoms or adverse
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47 448 effects, such as weight loss in the HIV/AIDS context, were referred back to the facility to be
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49 449 assessed by a nurse, and that all club participants saw a facility nurse at least once a year for
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51 450 their regular clinical check-up.

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3 452 In the CLUBMEDS study, we will assess if a similar club-based intervention is feasible and
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5 453 effective in improving BP control in the context of hypertension in Nigeria. Although the
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7 454 CLUBMEDS strategy has the potential to address several barriers to adherence to anti-
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9 455 hypertensive medications, this study has several limitations. First, this is study is a small
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11 456 feasibility study and, as such, a convenient sample of 100 patients was chosen to be included
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13 457 in the study. Second, the inclusion of both non-adherent and adherent patients in the study
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15 458 might limit the efficacy of the intervention, as adherent patients might not benefit from the
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17 459 intervention as much as non-adherent patients. Third, due to cultural norms, the presence of
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19 460 both men and women as club members might interfere with how these people share their
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21 461 challenges and concerns about adherence in the presence of people from the opposite sex in
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23 462 the monthly club meetings. However, the post-implementation process evaluation will be able
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25 463 to determine whether this was an interfering factor on the participation and success of the
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27 464 CLUBMEDS strategy. Last, financial constraints, medication shortages and the lack of
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29 465 pharmacists, pharmacist assistants, nurses or CHEWs responsible for pre-packing the
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31 466 medications in the primary healthcare facilities might limit the scalability of this strategy to
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33 467 other regions of Nigeria and other SSA countries.
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44 469 If shown to be effective and acceptable to the patients and other stakeholders, the CLUBMEDS
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46 470 strategy has the potential to change the current hypertension scenario, especially in resource-
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48 471 limited settings like many SSA countries, including Nigeria. The CLUBMEDS strategy has the
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50 472 potential of delivering a better care to patients with hypertension, by involving them, their
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52 473 relatives and their communities in their healthcare. With this engagement, we aim to improve
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54 474 the patients' knowledge about hypertension, encourage medication adherence and facilitate
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56 475 medication delivering, bringing the medications closer to the patients.
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5 477 **CONCLUSION**

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8 478 With the growing burden of hypertension in Nigeria and other LMICs, a change in the current
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10 479 model of hypertension management and treatment from the healthcare facility to community,
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12 480 is imperative. If we are to achieve the '25 x 25' World Heart Federation and World Health
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14 481 Organisation target of reducing premature cardiovascular disease mortality by 25% by 2025
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16 482 worldwide, we need to accelerate our efforts in bringing anti-hypertensive treatment closer to
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18 483 the population and ensure that at least 50% of eligible people are receiving medications to
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20 484 prevent heart attacks and strokes. A club-based strategy, which was shown to be effective and
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22 485 acceptable in the HIV/AIDS context, can similarly improve provision of care and treatment to
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24 486 hypertensive patients in resource-limited areas in LMICs. The CLUBMEDS study aims to
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26 487 evaluate a similar club-based strategy in patients with hypertension in Nigeria, where
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28 488 hypertension awareness, treatment and control remains suboptimal. The CLUBMEDS pilot
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30 489 study together with the formative and process qualitative evaluations will provide important
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32 490 preliminary data on the potential implementation of this approach in the hypertension context.
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34 491 If this strategy is shown to be feasible and acceptable, future studies may test the effectiveness
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36 492 of this strategy to improve BP control and longer-term medication adherence in LMICs, such
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38 493 as Nigeria. The CLUBMEDS findings will add to the body of evidence supporting adherence
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40 494 clubs as a way to overcome barriers to optimal treatment adherence.
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51 496 **DECLARATIONS**52
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54 497 **Statement**
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16 503 **Ethics approval**

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19 504 The study was approved by the Human Research Ethics Committees from the University of
20
21 505 Abuja Teaching Hospital (UATH/HREC/PR/2017/012/001) and the Federal Teaching Hospital
22
23 506 Abakaliki (FETHA/REC/VOL 2/2018/008) and all patients provided informed consent.
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30 508 **Competing interests**

31
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34 510 and/or publication of this article.
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52 516 **Authors' contributors**

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56
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58
59 519 subsequent meetings through the World Heart Federation Emerging Leaders Programme. GCI,
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5 521 manuscript. All authors critically revised the manuscript and approved the final manuscript.
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23 528 research.
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30 624 **Figure 1: A model of club-based medication delivery strategy in hypertension context**
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32 625 **from CLUBMEDS Study being implemented in Nigeria**

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35 626 Note: P refers to a patient or club member.
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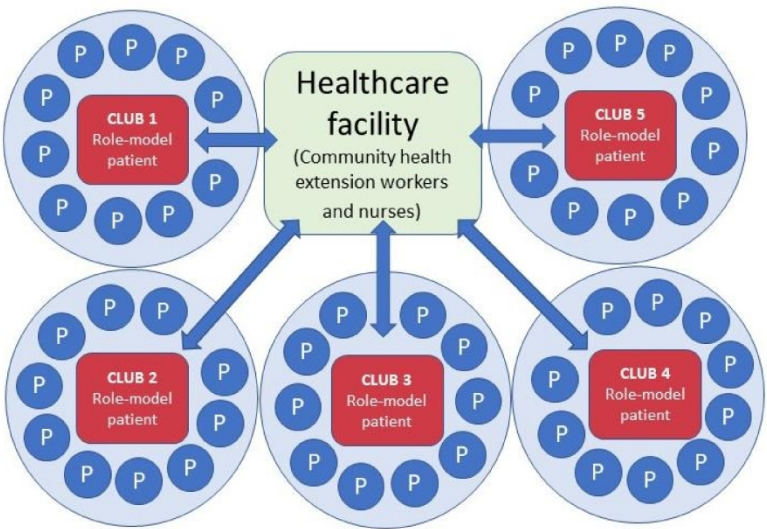


Figure 1: A model of club-based medication delivery strategy in hypertension context from CLUBMEDS Study being implemented in Nigeria

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