## WEBVTT

- $1\ 00:00:00.000 \longrightarrow 00:00:03.250$  (attendees chattering)
- 2 00:00:14.974 --> 00:00:19.057 (attendees chattering continues)
- 3 00:00:22.566 --> 00:00:25.483 <<br/>v ->Thanks.<br/></v> <<br/>v ->Thank you for your help.<br/></v>
- 4 00:00:28.340 --> 00:00:30.606 <v Donna>Hey, Ericka, how are you?</v>
- 5 00:00:30.606 --> 00:00:33.206 <v -> Good, how are you? </v> <v -> Good, thank you. </v>
- 6 00:00:33.206 --> 00:00:34.937 <<br/>v ->Hey-</v> <v ->So you must be Vilma?</v>
- 7~00:00:34.937 --> 00:00:36.840 < v -> Yes, I'm Vilma. < / v >< v -> Hello, < / v >
- $8~00:00:36.840 \longrightarrow 00:00:37.860$  my name is Luke Davis.
- 9 00:00:37.860 --> 00:00:40.788 Nice to meet you. (laughs)  $<\!\!\mathrm{v}$  ->Hello, Spanish... (laughs)  $<\!\!\mathrm{v}$  ->
- $10\ 00:00:40.788 --> 00:00:42.903 < v -> Yeah, I just came to welcome you. </v>$
- 11 00:00:44.046 --> 00:00:47.560 So I know trying set up with your presentation,
- $12\ 00{:}00{:}47.560 \dashrightarrow 00{:}00{:}49.726$  but I would wanna have a chance to join you and Donna
- $13\ 00:00:49.726 \longrightarrow 00:00:51.309$  for dinner tonight?
- $14\ 00:00:52.173 \longrightarrow 00:00:53.114 < v \longrightarrow Oh$ , but not today.
- $15\ 00:00:53.114 \longrightarrow 00:00:56.339$  I'm so late, so we can't have that now.
- 16 00:00:56.339 --> 00:00:58.033 <v -> I'd love to hear more-</v> <v -> We're working on many,</v>
- $17\ 00:00:58.033 \longrightarrow 00:00:59.749$  many things.  $\langle v \rangle I'd$  love to hear more,  $\langle /v \rangle$
- $18\ 00:00:59.749 --> 00:01:01.173$  and of course I'll learn a lot now,
- 19 00:01:01.173 --> 00:01:02.368 and I know you're doing a lot of education-
- 20 00:01:02.368 --> 00:01:03.376 <<br/>v ->Well, you know...</br/>/v> <v ->I just wanna...</v>
- 21 00:01:03.376 --> 00:01:04.818 <v Vilma>Yeah, that's good.</v>
- $22\ 00:01:04.818 --> 00:01:06.528$  Some other time. < v -> Well, remember, < / v >

- $25~00:01:09.390 \dashrightarrow 00:01:11.790$  so if you wanna go to the podium and choose-
- 26 00:01:11.790 --> 00:01:12.660 < v ->Oh, I see.</v> < v ->You have to do it</v>
- 27 00:01:12.660 --> 00:01:14.604 at the podium, yeah. (laughs) (Vilma laughing)
- 28 00:01:14.604 --> 00:01:16.754 <<br/>v Vilma>All right, I'll go to the podium then. (laughs)</r>
- 29 00:01:16.754 --> 00:01:21.754 <v -> Oh, okay. (Vilma laughing)</v>
- 30 00:01:23.834 --> 00:01:26.084 <v ->So are you ready?</v> <v ->Yeah.</v>
- 31 00:01:27.667 --> 00:01:28.500 <v Donna>It's only 12:01.</v>
- $32\ 00:01:28.500 --> 00:01:30.139$  We usually give people a little more time
- 34 00:01:36.270 --> 00:01:38.770 <v ->Yeah, we usually do.</v> <v ->Okay.</v>
- 35 00:01:40.528 --> 00:01:41.361 <v Donna>Hmm...</v>
- 36 00:01:41.361 --> 00:01:44.194 (papers rustling)
- 37 00:01:46.552 --> 00:01:47.718 Do you want me to put it in the chat
- 38 00:01:47.718 --> 00:01:50.319 that we'll start in about five minutes?
- $39\ 00:01:50.319 --> 00:01:51.777 < v \text{ Ericka} > I \text{ can be do that now.} < /v > 1$
- $40\ 00:01:51.777 --> 00:01:54.126 < v Donna>Can they hear us right now?</v>$
- $41\ 00:01:54.126 --> 00:01:55.958 < v$  Ericka> Yeah, we're not muted.</v>
- $42\ 00:01:55.958 --> 00:01:57.060 < v -> Okay, yeah, so hi, everyone. < / v >$
- $43\ 00:01:57.060 --> 00:02:00.227$  We're just gonna give people a few more minutes to arrive.
- $44~00:04:51.570 \longrightarrow 00:04:53.310~\mathrm{Hi}$ , everyone, I'm Donna Spiegelman.
- $45~00{:}04{:}53.310 \dashrightarrow 00{:}04{:}55.230$  I'm Director of the Center for Methods
- 46 00:04:55.230 --> 00:04:57.690 in Implementation and Prevention Science,
- $47\ 00:04:57.690 --> 00:05:01.290$  and I'm very pleased today to introduce our speaker,
- $48\ 00:05:01.290 --> 00:05:04.350$  Vilma Irazola, who is the Director
- $49~00:05:04.350 \dashrightarrow 00:05:06.660$  of the South American Center of Excellence
- $50\ 00:05:06.660 \longrightarrow 00:05:09.930$  for Cardiovascular Health and the Institute

- 51 00:05:09.930 --> 00:05:12.150 for Clinical Effectiveness and Health Policy,
- $52\ 00:05:12.150 --> 00:05:14.940$  both in Buenos Aires, Argentina.
- $53\ 00:05:14.940 \longrightarrow 00:05:16.470$  She's also deputy director
- 54~00:05:16.470 --> 00:05:19.770 of the master's degree program in Clinical Effectiveness
- $55\ 00:05:19.770 \longrightarrow 00:05:22.560$  at the University of Buenos Aires.
- $56\ 00:05:22.560 \longrightarrow 00:05:25.200$  She'll be speaking on, "Implementation Science:
- $57\ 00:05:25.200$  --> 00:05:28.410 Lessons learned from low- and middle-income countries
- $58\ 00:05:28.410 --> 00:05:30.090$  and new challenges."
- $59~00:05:30.090 \longrightarrow 00:05:31.710$  And I'm very pleased that this seminar
- $60\ 00:05:31.710$  --> 00:05:34.980 is co-sponsored by Yale School of Public Health's
- 61 00:05:34.980 --> 00:05:37.920 Department of Chronic Disease Epidemiology,
- $62\ 00:05:37.920 \longrightarrow 00:05:40.980$  and by the Yale Institute for Global Health
- 63 00:05:40.980 --> 00:05:42.660 at the Yale School of Medicine,
- $64~00{:}05{:}42.660 \dashrightarrow 00{:}05{:}44.640$  and by Cardiovascular Medicine
- $65\ 00:05:44.640 \longrightarrow 00:05:46.020$  at the Yale School of Medicine
- 66 00:05:46.020 --> 00:05:50.160 and finally, by our NIH T32 Training Grant
- $67\ 00:05:50.160 --> 00:05:53.643$  in Implementation Science Research Methods from NHLBI.
- $68\ 00:05:56.850 \longrightarrow 00:05:59.943$  Vilma is a cardiologist and epidemiologist.
- $69\ 00:06:01.410 --> 00:06:04.070$  Her research is focused on implementation science
- $70\ 00:06:04.070 \longrightarrow 00:06:06.930$  in the area of public health, health promotion
- $71~00{:}06{:}06{.}930 \dashrightarrow 00{:}06{:}10.020$  and prevention and management of chronic diseases.
- $72\ 00:06:10.020 \dashrightarrow 00:06:12.780$  She has been involved in the design and evaluation
- 73 00:06:12.780 --> 00:06:15.720 of community-based and primary care programs
- $74\ 00:06:15.720 \longrightarrow 00:06:18.930$  and interventions related to cardiovascular disease,
- 75 00:06:18.930 --> 00:06:20.493 diabetes and aging.

- 76 00:06:21.360 --> 00:06:23.490 In addition to her work in Argentina,
- $77\ 00:06:23.490 \longrightarrow 00:06:24.540$  where she also teaches
- 78~00:06:24.540 --> 00:06:27.630 Advanced Epidemiologic and Analytic Methods,
- 79~00:06:27.630 --> 00:06:32.550 she is Associate Professor of the Cross-Continental MPH
- 80 00:06:32.550 --> 00:06:35.550 at the College of Global Public Health at NYU,
- $81\ 00:06:35.550 \longrightarrow 00:06:36.840$  and a scholar and lecturer
- $82\ 00:06:36.840 --> 00:06:38.790$  at the Harvard School of Public Health.
- 83 00:06:38.790 --> 00:06:41.307 I've known Vilma, I don't know, for how many years?
- 84 00:06:41.307 --> 00:06:43.500 15, 20, maybe more.
- 85 00:06:43.500 --> 00:06:45.780 We originally met at Harvard
- 86 00:06:45.780 --> 00:06:48.000 in connection with the Lown Scholars Program,
- 87~00:06:48.000 --> 00:06:51.120 among other things, and I think the last time I saw her
- $88\ 00:06:51.120 --> 00:06:53.580$  was in Guatemala before COVID,
- $89\ 00:06:53.580 \longrightarrow 00:06:57.900$  where we were both working in a consortium of projects
- $90\ 00:06:57.900 \longrightarrow 00:07:02.900$  to scale up and implement cardiovascular disease prevention,
- 91 00:07:03.900 --> 00:07:06.900 screening and treatment programs around the world,
- $92\ 00:07:06.900 \longrightarrow 00:07:11.520$  a consortium that was sponsored by NHLBI.
- 93 00:07:11.520 --> 00:07:13.530 So I'm happy to turn things over to Vilma,
- 94 00:07:13.530 --> 00:07:16.860 and I'm looking forward to your talk.
- 95 00:07:16.860 --> 00:07:18.143 <v -> Thank you.</v>
- 96 00:07:18.143 --> 00:07:20.321 Thank you, thank you very much, Donna.
- 97 00:07:20.321 --> 00:07:22.362 And thank you for invitation
- $98\ 00:07:22.362 \longrightarrow 00:07:25.930$  and for this opportunity to share some topics
- $99\ 00:07:27.120 \longrightarrow 00:07:30.400$  that we are working on and to listen to you
- $100\ 00:07:30.400 \longrightarrow 00:07:33.600$  and your experiences as well.
- 101 00:07:33.600 --> 00:07:35.070 So for today,

- $102\ 00:07:35.070 --> 00:07:39.570$  I will share a brief presentation
- $103\ 00:07:39.570 \longrightarrow 00:07:44.010$  about some topics that I'd like to share with you today,
- 104 00:07:44.010 --> 00:07:47.317 and I will share my screen in a minute.
- $105\ 00:07:51.838 \longrightarrow 00:07:53.171$  Oh, there it is.
- $106\ 00:08:05.101 \longrightarrow 00:08:10.101$  Okay, so what's the idea today?
- 107 00:08:11.340 --> 00:08:12.570 What's the topic?
- 108 00:08:12.570 --> 00:08:14.610 This morning actually, Donna and I
- $109\ 00:08:14.610 --> 00:08:17.400$  were talking about some aspects
- $110\ 00:08:17.400 \longrightarrow 00:08:21.720$  that are so relevant for our work in implementation science,
- 111 00:08:21.720 --> 00:08:26.720 and about which we don't have, still,
- $112\ 00:08:27.630 \longrightarrow 00:08:29.760$  maybe all the methods and tools
- $113\ 00:08:29.760 \longrightarrow 00:08:33.360$  that we may need to approach that.
- $114\ 00:08:33.360 \longrightarrow 00:08:35.220$  So the idea is, today,
- $115\ 00:08:35.220 \longrightarrow 00:08:37.407$  to talk about the role of the control group
- 116 00:08:37.407 --> 00:08:39.780 and how to evaluate the control group
- 117 00:08:39.780 --> 00:08:43.590 in our implementation science studies,
- $118\ 00:08:43.590 \longrightarrow 00:08:47.640$  the role of context evaluation in this approach
- 119 00:08:47.640 --> 00:08:50.290 and the concept of usual care and enhanced usual care
- 120 00:08:52.582 --> 00:08:53.613 in our project.
- 121 00:08:54.750 --> 00:08:59.750 To do this, I will use two examples from our work
- $122\ 00:09:00.900$  --> 00:09:05.370 in Argentina connected with hypertension control.
- $123\ 00{:}09{:}05.370 \dashrightarrow 00{:}09{:}08.970$  These are two cluster-randomized controlled trials
- $124\ 00:09:08.970 \longrightarrow 00:09:12.930$  that we have conducted.
- $125\ 00:09:12.930 \longrightarrow 00:09:17.930$  One of them is finished and the other one is ongoing.
- 126 00:09:21.690 --> 00:09:24.660 Well, in terms of context evaluation,

- $127\ 00{:}09{:}24.660 \dashrightarrow 00{:}09{:}28.020$  we all are familiar with the different frameworks
- $128\ 00:09:28.020 --> 00:09:31.985$  that we usually use to approach this topic,
- 129 00:09:31.985 --> 00:09:33.843 like CFIR, for example,
- $130\ 00:09:34.890 \longrightarrow 00:09:39.183$  which is one of the first ones that approach, in depth,
- $131\ 00:09:40.530 \longrightarrow 00:09:45.093$  the evaluation of outer and inner settings.
- $132\ 00:09:46.530 \longrightarrow 00:09:49.050$  I am sure you are also familiar
- $133\ 00:09:49.050 --> 00:09:51.930$  with the RE-AIM-PRISM framework, you know,
- $134\ 00:09:51.930 --> 00:09:56.723$  that Dr. Glasgow, who is the developer of the framework,
- $135~00{:}10{:}03.570 \dashrightarrow 00{:}10{:}08.570~\text{I'd}$  say expanded this framework into RE-AIM-PRISM
- $136\ 00{:}10{:}14.128 {\:{\mbox{--}}\!>}\ 00{:}10{:}18.743$  to include more aspects related to the context evaluation
- $137\ 00:10:20.430 \longrightarrow 00:10:22.440$  for this framework,
- $138\ 00:10:22.440 \longrightarrow 00:10:24.993$  which in the past was more focused
- $139\ 00{:}10{:}24.993 \dashrightarrow 00{:}10{:}29.993$  only on evaluation and the different aspects of evaluation,
- $140\ 00:10:30.510 \longrightarrow 00:10:32.670$  in terms of reach, effectiveness,
- $141\ 00:10:32.670 \longrightarrow 00:10:35.013$  adoption, implementation among many.
- $142\ 00{:}10{:}35.940 \dashrightarrow 00{:}10{:}39.583$  With RE-AIM-PRISM. we working today several projects
- 143 00:10:39.583 --> 00:10:42.833 in Argentina and Brazil and Guatemala,
- 144 00:10:44.790 --> 00:10:47.070 and we find it really useful
- $145\ 00:10:47.070 \longrightarrow 00:10:49.710$  for all these other topics that were added
- $146\ 00:10:49.710 --> 00:10:51.690$  to the original RE-AIM framework.
- $147\ 00:10:52.987 \dashrightarrow 00:10:56.427$  And also, I'd like to share with you this framework,
- $148\ 00:10:57.369 \longrightarrow 00:10:59.573$  which is the CIIP.
- $149\ 00:10:59.573 --> 00:11:03.156$  This is a framework that, as far as I know,
- $150\ 00{:}11{:}04.228 {\:\hbox{--}}{>}\ 00{:}11{:}08.330$  is not very commonly used in implementation research,

- 151 00:11:08.330 --> 00:11:11.127 it is more commonly used in training,
- 152 00:11:11.127 --> 00:11:14.507 in training projects and programs.
- $153\ 00{:}11{:}14.507 \dashrightarrow 00{:}11{:}17.997$  And I think that there are several things in this framework
- $154\ 00:11:17.997 --> 00:11:21.920$  that may be useful for us, as implementation researchers,
- $155\ 00:11:21.920 \longrightarrow 00:11:25.503$  to adopt and to incorporate to our methods.
- $156\ 00{:}11{:}26.613 \dashrightarrow 00{:}11{:}31.196$  And one thing that I find really interesting about CIIP
- 157 00:11:32.964 --> 00:11:35.480 is that the context evaluation,
- 158 00:11:35.480 --> 00:11:39.001 which is the first step in this framework,
- $159\ 00:11:39.001 \longrightarrow 00:11:43.376$  is then translated into the different stages
- $160\ 00:11:43.376 \longrightarrow 00:11:44.509$  in the framework.
- 161 00:11:44.509 --> 00:11:47.209 So according to this framework,
- $162\ 00:11:47.209 --> 00:11:51.509$  we keep evaluating the context throughout the project.
- 163 00:11:51.509 --> 00:11:55.433 In this case, they are usually education
- $164\ 00:11:55.433 \longrightarrow 00:11:59.016$  or training projects, but the proposal here
- $165\ 00:12:00.370 \longrightarrow 00:12:04.090$  is to keep evaluating these dynamic contexts
- $166\ 00:12:05.100 \longrightarrow 00:12:08.040$  throughout the project and beyond.
- $167\ 00:12:08.040 \longrightarrow 00:12:12.450$  So that's something that might be really useful
- $168\ 00{:}12{:}12.450 \dashrightarrow 00{:}12{:}17.450$  and interesting for us as implementation researchers.
- $169\ 00:12:18.537 \ --> \ 00:12:23.070$  And this brief introduction about context evaluation
- $170\ 00:12:23.070 \longrightarrow 00:12:26.490$  is connected with the role
- $171\ 00:12:26.490 \longrightarrow 00:12:31.490$  that this type of evaluation might have
- $172\ 00:12:32.250 \longrightarrow 00:12:37.077$  in the description and approach
- $173\ 00{:}12{:}37.077 \dashrightarrow 00{:}12{:}41.277$  to the definition of usual care or enhanced usual care
- 174 00:12:41.277 --> 00:12:43.197 in our project.
- 175 00:12:43.197 --> 00:12:44.550 And to go into this topic,

 $176\ 00:12:44.550 \longrightarrow 00:12:49.550$  I'd like to share with you an example of a trial,

177 00:12:49.746 --> 00:12:51.763 a cluster-randomized controlled trial,

 $178\ 00{:}12{:}51.763 \dashrightarrow 00{:}12{:}56.763$  that we conducted in Argentina a few years ago.

 $179\ 00{:}12{:}56.863 \dashrightarrow 00{:}13{:}01.863$  It was about testing a comprehensive intervention

180 00:13:02.513 --> 00:13:06.388 for improving hypertension control

181 00:13:06.388 --> 00:13:10.996 in vulnerable population in our country.

 $182\ 00{:}13{:}10.996 \dashrightarrow 00{:}13{:}15.278$  You know that hypertension is a leading global risk factor

183 00:13:15.278 --> 00:13:19.180 for cardiovascular disease and death,

184 00:13:19.180 --> 00:13:24.180 and about 75% of people with hypertension

 $185\ 00:13:25.680 \longrightarrow 00:13:29.730$  live in low- and middle income countries.

186 00:13:29.730 --> 00:13:32.274 And this, again, is pre-pandemic.

 $187\ 00:13:32.274 \longrightarrow 00:13:36.573$  After the pandemic, it's even worse.

 $188\ 00{:}13{:}37.830 \dashrightarrow 00{:}13{:}40.830$  The other thing that is very important and critical for us

189~00:13:40.830 --> 00:13:45.830 is that less than 10% hypertensive patients in our countries

 $190\ 00:13:46.920 \longrightarrow 00:13:48.790$  are under control,

191 00:13:48.790 --> 00:13:53.110 or have their blood pressure under control.

 $192\ 00:13:53.110 \longrightarrow 00:13:55.676$  In the case of Argentina,

 $193\ 00:13:55.676 \longrightarrow 00:13:59.760$  the control rate is about 18%,

 $194\ 00:13:59.760 \longrightarrow 00:14:04.760$  according to our last estimations, again, prepandemic.

195 00:14:05.760 --> 00:14:10.760 We have some data from 2021 and early this year

 $196\ 00:14:11.932 \dashrightarrow 00:14:16.932$  which indicates that the control rate is even worse.

197 00:14:19.484 --> 00:14:20.901 Well, so briefly,

 $198\ 00:14:22.173 --> 00:14:27.173$  in this trial we selected 18 primary care clinics

 $199\ 00:14:27.330 \longrightarrow 00:14:30.900$  in different provinces in the country,

- $200\ 00:14:30.900 \longrightarrow 00:14:35.900$  and included participants who were adults with hypertension,
- 201 00:14:38.400 --> 00:14:40.360 who were really controlled,
- 202 00:14:40.360 --> 00:14:44.790 and defined full control of hypertension
- 203 00:14:44.790 --> 00:14:47.430 as having a systolic blood pressure
- $204\ 00:14:47.430 \longrightarrow 00:14:52.430$  of 140 millimeters of mercury, or above that number,
- $205\ 00:14:54.373 --> 00:14:56.951$  and/or a diastolic blood pressure
- 206 00:14:56.951 --> 00:14:59.368 of 90 millimeters of mercury.
- 207 00:15:00.510 --> 00:15:03.595 We included these patients,
- 208 00:15:03.595 --> 00:15:07.140 their spouses, with or without hypertension,
- $209\ 00:15:07.140 --> 00:15:10.170$  because part of the intervention
- $210\ 00:15:10.170 \longrightarrow 00:15:13.530$  was related to the role of peers,
- 211 00:15:13.530 --> 00:15:16.500 family members and people living
- $212\ 00{:}15{:}16.500 \longrightarrow 00{:}15{:}19.269$  with these hypertensive patients,
- $213\ 00{:}15{:}19.269 \dashrightarrow 00{:}15{:}24.150$  and also, any other adult hypertensive family member
- $214\ 00:15:24.150 \longrightarrow 00:15:26.820$  living in the same household.
- 215 00:15:26.820 --> 00:15:29.793 That was the population of the study.
- $216\ 00{:}15{:}30.957 \dashrightarrow 00{:}15{:}33.963$  And this is, again, briefly the flow chart of the trial.
- $217\ 00:15:37.680 --> 00:15:42.660$  We included 18 public primary care clinics
- $218\ 00:15:42.660 \longrightarrow 00:15:47.455$  that were randomized to the intervention or the control.
- $219\ 00:15:47.455 \longrightarrow 00:15:50.490$  And here is the topic, the control arm.
- $220\ 00{:}15{:}50.490 \dashrightarrow 00{:}15{:}55.200$  We conducted measurements at baseline six, 12 and 18 months,
- 221 00:15:57.613 --> 00:15:59.730 the outcomes of the study,
- $222\ 00{:}15{:}59.730 \dashrightarrow 00{:}16{:}04.680$  for changes in systolic and diastolic blood pressure
- $223\ 00:16:04.680 \longrightarrow 00:16:06.830$  and hypertension control rate at 18 months.
- $224\ 00:16:11.520 \longrightarrow 00:16:14.700$  And this is a summary of the intervention.
- $225\ 00:16:14.700 --> 00:16:17.130$  We defined three main components.

- $226\ 00{:}16{:}17.130 \longrightarrow 00{:}16{:}20.400$  The most important one was connected
- 227 00:16:20.400 --> 00:16:23.549 with the role of community health workers
- 228 00:16:23.549 --> 00:16:27.743 working as part of the primary care team
- $229\ 00:16:27.743 \longrightarrow 00:16:32.310$  and working with the participants, with the patients,
- $230\ 00:16:32.310 \longrightarrow 00:16:34.290$  at their homes.
- 231 00:16:34.290 --> 00:16:35.580 In this intervention,
- $232\ 00:16:35.580 \longrightarrow 00:16:38.693$  community health workers visited patients at their homes,
- $233\ 00:16:41.700 \longrightarrow 00:16:44.910$  working with their family as well.
- 234 00:16:44.910 --> 00:16:48.780 Patients were provided with BP monitors
- $235\ 00:16:48.780 \longrightarrow 00:16:52.770$  to self-monitor their blood pressure.
- $236\ 00:16:52.770 \longrightarrow 00:16:55.770$  Community health workers trained them
- $237\ 00:16:55.770 \longrightarrow 00:16:59.160$  on how to use these devices
- 238 00:16:59.160 --> 00:17:02.640 and to monitor their blood pressure.
- 239 00:17:02.640 --> 00:17:05.285 They, community health workers,
- 240 00:17:05.285 --> 00:17:09.390 also provided information and tools,
- $241\ 00:17:09.390 \dashrightarrow 00:17:13.701$  different tools to improve medication adherence
- $242\ 00:17:13.701 \longrightarrow 00:17:17.340$  and lifestyle modifications.
- $243\ 00{:}17{:}17.340 \dashrightarrow 00{:}17{:}21.833$  So mainly this part of the intervention was very important
- 244 00:17:21.833 --> 00:17:25.090 and was led by community health workers
- $245\ 00:17:26.550 \longrightarrow 00:17:28.803$  that were trained to do that.
- $246\ 00{:}17{:}30.691 \dashrightarrow 00{:}17{:}34.860$  The other component was an mHealth component.
- $247\ 00:17:34.860 --> 00:17:38.730$  We sent messages, text messages,
- 248 00:17:38.730 --> 00:17:43.730 to participants about lifestyle modifications,
- $249\ 00:17:44.490 \longrightarrow 00:17:48.443$  mainly diet and physical activity, that was the focus,
- $250\ 00:17:49.407 --> 00:17:52.830$  and again, medication adherence.
- $251\ 00{:}17{:}52.830 \dashrightarrow 00{:}17{:}56.883$  And the third component was directed to physicians,

- 252 00:18:00.211 --> 00:18:02.740 primary care physicians.
- 253 00:18:02.740 --> 00:18:05.724 Primary care physicians were trained
- 254 00:18:05.724 --> 00:18:09.290 in the use of clinical practice guidelines
- 255 00:18:09.290 --> 00:18:13.040 and they also received information, feedback,
- $256\ 00{:}18{:}14.340 \dashrightarrow 00{:}18{:}18.633$  about the blood pressure values of their patients.
- $257\ 00:18:20.100 --> 00:18:25.100$  What they did when they saw the blood pressure values
- $258\ 00{:}18{:}29.790$  -->  $00{:}18{:}34.770$  of their patients was something that they decided
- $259\ 00:18:34.770 \longrightarrow 00:18:35.603$  by their own.
- 260 00:18:38.140 --> 00:18:41.940 Apart from an initial training on the use
- 261 00:18:41.940 --> 00:18:45.720 and contents of clinical practice guidelines,
- $262\ 00:18:45.720 --> 00:18:50.310$  we did not do anything else with decisions.
- $263\ 00:18:50.310 \longrightarrow 00:18:55.107$  So they decided what to do, how to manage their patients,
- $264\ 00:18:55.107 --> 00:18:58.075$  but they received this information
- $265\ 00:18:58.075 --> 00:19:01.158$  that is not part of the initial care.
- 267 00:19:03.120 --> 00:19:03.953 <v Donna>Can you say</v>
- 268 00:19:03.953 --> 00:19:07.080 what blood pressure audit and feedback is?
- 269 00:19:07.080 --> 00:19:09.660 < v ->Yes.</v> < v ->That's the second component.</v>
- $270\ 00:19:09.660 --> 00:19:11.973 < v -> Yes$ , that's the second component. </v>
- $271\ 00:19:12.930 --> 00:19:16.390$  What we did is the community health worker
- 272 00:19:18.240 --> 00:19:20.730 visited patient's home each month
- $273\ 00:19:20.730 \dashrightarrow 00:19:23.913$  during the first six months, and then bimonthly.
- 274 00:19:25.440 --> 00:19:28.830 When they went to a patient's home,
- 275 00:19:28.830 --> 00:19:31.250 they reviewed, with the patient,
- 276 00:19:31.250 --> 00:19:35.336 all the values of their blood pressure,
- $277\ 00:19:35.336 \longrightarrow 00:19:37.188$  according to a log

 $278\ 00:19:37.188 \longrightarrow 00:19:40.938$  that the participants were asked to complete.

279 00:19:41.940 --> 00:19:45.000 And that information was shared

 $280\ 00:19:45.000 \longrightarrow 00:19:48.630$  by the community health worker with the physician.

281 00:19:48.630 --> 00:19:50.064 That's the feedback,

 $282\ 00:19:50.064 \longrightarrow 00:19:55.064$  that's the component of sharing data with the physician.

 $283\ 00:19:57.360 --> 00:20:02.360$  And that's all what we did in that component.

284 00:20:03.960 --> 00:20:06.900 Some physicians were very proactive,

 $285\ 00{:}20{:}06.900 \dashrightarrow 00{:}20{:}10.740$  and they take action and adjust medication, et cetera,

 $286\ 00:20:10.740 \longrightarrow 00:20:12.630$  and others not.

287 00:20:12.630 --> 00:20:16.330 We haven't had nothing to do directly

 $288\ 00:20:17.430 \longrightarrow 00:20:20.460$  through the trial with that.

 $289\ 00:20:20.460 \longrightarrow 00:20:22.083$  So that was that component.

290 00:20:23.670 --> 00:20:26.370 And it's important to your question, Donna,

291 00:20:26.370 --> 00:20:27.493 because at the time,

292 00:20:27.493 --> 00:20:32.400 there were no electronic medical records in these clinics.

 $293\ 00:20:32.400 \longrightarrow 00:20:36.330$  Now, in these provinces, the situation is different,

 $294\ 00:20:36.330 \longrightarrow 00:20:40.563$  so we would be able to do this differently now.

295 00:20:42.060 --> 00:20:45.327 And I can tell you what's happening now

 $296\ 00:20:45.327 \longrightarrow 00:20:47.577$  in these provinces as well.

 $297\ 00:20:49.411 --> 00:20:53.260$  Well, so these are briefly the three components

 $298\ 00:20:54.180 \longrightarrow 00:20:56.343$  of the intervention.

 $299~00{:}20{:}57.485 \dashrightarrow 00{:}21{:}02.290$  This is, for example, a picture of the training sessions

 $300\ 00{:}21{:}03.420 \dashrightarrow 00{:}21{:}06.873$  for community health workers at the university,

 $301\ 00:21:08.667 --> 00:21:12.570$  and these are some examples of the tools

 $302\ 00{:}21{:}12.570 \dashrightarrow 00{:}21{:}17.570$  that the community health worker share with participants,

- 303 00:21:18.355 --> 00:21:20.355 for example, pill boxes,
- $304\ 00:21:23.071 --> 00:21:26.488$  to help improving adherence to medication
- $305\ 00:21:28.471 \longrightarrow 00:21:33.471$  and other tools that they share with patients as well.
- $306~00{:}21{:}36.570 \dashrightarrow 00{:}21{:}41.029$  They, community health workers, trained participants
- $307\ 00:21:41.029 \longrightarrow 00:21:45.946$  on how to measure and monitor their blood pressure as well.
- 308 00:21:48.510 --> 00:21:51.123 And everything happened at home.
- $309\ 00:21:53.520 \longrightarrow 00:21:57.753$  Well, some of the results, what happened with this trial?
- 310 00:21:59.809 --> 00:22:00.642 In this table,
- 311 00:22:00.642 --> 00:22:05.642 we describe the main characteristics of our participants.
- $312\ 00:22:05.790 \longrightarrow 00:22:10.790$  As you can see, the mean age was around 56 years old,
- $313\ 00:22:16.170 \longrightarrow 00:22:17.320$  half of them were women
- $314\ 00:22:19.473 \longrightarrow 00:22:24.150$  and what else I'd like to highlight here
- 315 00:22:24.150 --> 00:22:26.220 were patients were poorly controlled,
- 316 00:22:26.220 --> 00:22:30.030 that was a criteria to enter the study.
- $317\ 00:22:30.030 \longrightarrow 00:22:32.370$  You can see also in this table
- $318\ 00:22:32.370 --> 00:22:35.850$  that the use of antihypertensive medication was very high.
- 319 00:22:38.033 --> 00:22:41.566 This is the public system in Argentina
- $320\ 00:22:41.566 --> 00:22:45.566$  and medication is provided for free to patients.
- $321\ 00:22:48.172 \longrightarrow 00:22:51.953$  The problem is that there are periods of time
- $322\ 00{:}23{:}00.664 \dashrightarrow 00{:}23{:}04.110$  where the centers don't have enough medication
- $323\ 00:23:04.110 \longrightarrow 00:23:04.943$  for patients.
- 324 00:23:04.943 --> 00:23:07.023 That's very frequent, that's very frequent.
- 325 00:23:07.860 --> 00:23:10.920 So in spite of being a high percentage,
- 326 00:23:10.920 --> 00:23:14.760 high proportion of patients being treated,
- $327\ 00:23:14.760 \longrightarrow 00:23:17.820$  the problem here was more connected

- 328 00:23:17.820 --> 00:23:21.393 with continuity of treatment,
- $329\ 00{:}23{:}22.830 \dashrightarrow 00{:}23{:}27.817$  in part because of lack of medication during some months.
- 330 00:23:27.817 --> 00:23:29.634 <v Donna>Can I make a comment right here on this?</v>
- 331 00:23:29.634 --> 00:23:31.020 <v ->Yes, sure.</v> <v ->So I see that you</v>
- 332 00:23:31.020 --> 00:23:33.960 sort of started off in a bad-luck situation,
- $333\ 00:23:33.960 \longrightarrow 00:23:36.160$  where the intervention group
- $334\ 00:23:37.170 --> 00:23:40.860$  had significantly higher history of CVD
- $335\ 00{:}23{:}40.860 \dashrightarrow 00{:}23{:}43.350$  and higher systolic and diastolic blood pressure.
- 336 00:23:43.350 --> 00:23:45.660 It's not huge differences,
- 337 00:23:45.660 --> 00:23:47.820 but usually with sample sizes like that,
- $338\ 00:23:47.820 --> 00:23:51.370$  you don't see significant differences in a randomized trial.
- 339 00:23:51.370 --> 00:23:52.770 < v ->Yeah.</v> < v ->But maybe it's because</v>
- $340\ 00{:}23{:}52.770 \dashrightarrow 00{:}23{:}56.400$  of the cluster randomization and there might have been...
- $341\ 00:23:56.400 --> 00:23:59.460\ I\ don't\ know\ what\ the\ ICC\ was\ with\ the\ clusters,$
- $342\ 00{:}23{:}59.460 \dashrightarrow 00{:}24{:}02.940$  but may be there was a lot of variation in the clusters,
- $343\ 00{:}24{:}02.940 --> 00{:}24{:}07.537$  so that it's much easier to have a bad-luck randomization
- $344\ 00:24:07.537 \longrightarrow 00:24:08.819$  like this. <v ->Yes.</v>
- $345\ 00:24:08.819 \longrightarrow 00:24:10.652$  It was just like that.
- 346 00:24:12.069 --> 00:24:16.113 And in our calculation, our sample size,
- $347\ 00:24:18.561 \longrightarrow 00:24:22.170$  we estimated an ICC of 0.06,
- 348 00:24:22.170 --> 00:24:24.960 that was our sample size calculation,
- 349 00:24:24.960 --> 00:24:27.723 but then, after conducting the trial,
- $350\ 00:24:29.443 \longrightarrow 00:24:31.053$  the actual ICC was 0.15.

- 351 00:24:32.994 --> 00:24:36.045 <v -> Wow, yeah that is-</v> <v -> It was very high.</v>
- $352\ 00:24:36.045 \longrightarrow 00:24:37.462$  It was very high.
- $353\ 00:24:39.450 \longrightarrow 00:24:43.920$  Well, so this is the population
- 354 00:24:43.920 --> 00:24:47.400 and what happened with our outcomes,
- $355\ 00{:}24{:}47.400$  -->  $00{:}24{:}52.400$  systolic, dia stolic blood pressure and hypertension control.
- $356\ 00:24:53.370 \longrightarrow 00:24:54.930$  Before going into that,
- 357 00:24:54.930 --> 00:24:58.950 I'd like to remind you that...
- 358~00:24:58.950 --> 00:25:02.040 Or not remind, I think I didn't say it.
- $359\ 00:25:02.040 \longrightarrow 00:25:03.800\ I\ think\ I\ didn't\ say\ it.$
- $360\ 00:25:03.800 \longrightarrow 00:25:07.870$  If can go back to the previous slide...
- $361\ 00:25:14.067 \longrightarrow 00:25:15.243$  But it doesn't matter.
- $362\ 00:25:16.530 \longrightarrow 00:25:20.250$  One important thing here, in terms of our topic today,
- $363\ 00:25:20.250 \longrightarrow 00:25:21.747$  which is the control group
- 364 00:25:21.747 --> 00:25:24.720 and how to evaluate the control group,
- 365 00:25:24.720 --> 00:25:29.040 is that we conducted evaluation visits,
- $366\ 00:25:29.040$  --> 00:25:34.040 study evaluation visits, at baseline six, 12 and 18 months.
- 367 00:25:35.776 --> 00:25:39.817 And who conducted those visits?
- 368 00:25:39.817 --> 00:25:43.110 We trained the study nurses
- 369 00:25:43.110 --> 00:25:45.900 who were part of the medical staff
- 370 00:25:45.900 --> 00:25:50.900 of the primary care team in each clinic,
- $371\ 00:25:51.840 \longrightarrow 00:25:56.520$  that is, the nurses in charge of conducting
- $372\ 00{:}25{:}56.520 {\: \hbox{--}}{>}\ 00{:}26{:}01.520$  the evaluation visits were part of the primary care team.
- 373 00:26:02.340 --> 00:26:04.740 And this is important later
- $374\ 00:26:04.740 \longrightarrow 00:26:08.160$  for the interpretation of our results.
- 376 00:26:10.350 --> 00:26:12.630 Was that by design or in retrospect?
- 377 00:26:12.630 --> 00:26:14.010 Maybe you wouldn't have preferred that?

- $378\ 00:26:14.010 \longrightarrow 00:26:16.530\ I$  mean, it seems like if they're part of the group,
- 379 00:26:16.530 --> 00:26:18.090 it might be hard for them to be objective.
- 380 00:26:18.090 --> 00:26:20.610 Is that the point that you're making?
- $381\ 00:26:20.610 \longrightarrow 00:26:23.070 < v \longrightarrow Yes, yes. < /v >$
- 382 00:26:23.070 --> 00:26:27.420 Yes, but it was so by design really,
- $383\ 00{:}26{:}27.420 \dashrightarrow 00{:}26{:}31.440$  because in my view, there is a trade-off here, you know?
- 384 00:26:31.440 --> 00:26:34.200 This is very warm, our population.
- $385\ 00:26:34.200 --> 00:26:37.710$  So sometimes it's difficult to enter
- $386\ 00{:}26{:}37.710 \dashrightarrow 00{:}26{:}42.180$  in the neighborhood and be accepted by people.
- $387\ 00:26:42.180 \longrightarrow 00:26:45.270$  People have to open their door
- 388 00:26:45.270 --> 00:26:50.270 for you to conduct these evaluations,
- $389\ 00:26:50.490 \longrightarrow 00:26:52.980$  and for them, it's very important
- $390\ 00:26:52.980 \longrightarrow 00:26:57.630$  that they know these people.
- $391\ 00:26:57.630 \longrightarrow 00:27:00.993$  So we thought a lot about that and said,
- $392\ 00:27:01.950 \longrightarrow 00:27:04.620$  "Well, we can hire nurses
- $393\ 00:27:04.620$  --> 00:27:09.620 and do this absolutely independent of the primary care team,
- 394 00:27:10.380 --> 00:27:12.540 but in our opinion,
- $395\ 00:27:12.540 --> 00:27:14.580$  it would have been very difficult
- 396 00:27:14.580 --> 00:27:17.397 for them to enter many of these houses."
- $397\ 00:27:18.356 \longrightarrow 00:27:23.356$  So we say, "Well, we trained, in depth and intensively,
- 398 00:27:25.770 --> 00:27:30.573 these nurses on how to make the evaluations,
- 399 00:27:31.500 --> 00:27:33.570 how to collect the data.
- 400 00:27:33.570 --> 00:27:36.670 They were trained not to do anything else
- 401 00:27:37.530 --> 00:27:40.713 when they conducted these evaluation visits,
- 402 00:27:41.700 --> 00:27:44.941 but they were part of the primary care team,
- $403\ 00:27:44.941 --> 00:27:48.963$  and people know that, so that's important, yeah,
- $404\ 00:27:51.480 --> 00:27:55.860$  Well, what happened then with our outcomes?

- $405\ 00:27:55.860 \longrightarrow 00:27:58.620$  We can see here the effect of the intervention
- $406\ 00:27:58.620 \longrightarrow 00:28:01.213$  on systolic blood pressure.
- $407\ 00{:}28{:}01.213 \dashrightarrow 00{:}28{:}06.213$  There was a significant reduction in the intervention group
- 408 00:28:10.350 --> 00:28:14.657 early at six months, and this effect was present
- $409\ 00:28:16.663 \longrightarrow 00:28:19.470$  until the end of the study as well.
- $410\ 00:28:19.470 \longrightarrow 00:28:21.870$  So we have these positive results,
- $411\ 00:28:21.870 \longrightarrow 00:28:25.351$  in terms of systolic blood pressure.
- 412 00:28:25.351 --> 00:28:28.991 But if you look at the control group here,
- 413 00:28:28.991 --> 00:28:33.487 the control group also presented improvement
- $414\ 00:28:38.477 \longrightarrow 00:28:42.503$  in the systolic blood pressure of their patients.
- $415\ 00{:}28{:}43.350 \dashrightarrow 00{:}28{:}48.180$  And the same happened with diastolic blood pressure.
- 41600:28:48.180 --> 00:28:51.090 The reduction was significantly different
- 417 00:28:51.090 --> 00:28:52.560 between the two groups,
- 418 00:28:52.560 --> 00:28:55.323 but again, in the control group,
- $419\ 00{:}28{:}56.340 {\: -->\:} 00{:}29{:}00.270$  there was an improvement, a significant improvement,
- $420\ 00:29:00.270 \longrightarrow 00:29:03.240$  within this arm.
- 421 00:29:03.240 --> 00:29:06.690 And same thing when we look
- $422\ 00:29:06.690 \longrightarrow 00:29:08.710$  into the proportion of participants
- $423\ 00:29:10.290 \longrightarrow 00:29:13.370$  with their blood pressure under control.
- $424\ 00:29:15.210 \longrightarrow 00:29:20.210$  Again, the difference was significant between the arms,
- $425\ 00{:}29{:}21.330 \dashrightarrow 00{:}29{:}24.873$  but there was improvement in the control group.
- $426\ 00{:}29{:}30.210 \longrightarrow 00{:}29{:}34.380$  Well these are some data about mediators,
- $427\ 00:29:34.380 \longrightarrow 00:29:39.380$  like adherence to medication, which was improved over time,
- $428\ 00{:}29{:}41.460 \dashrightarrow 00{:}29{:}46.460$  and the same happened with adjustment of medication
- $429\ 00:29:47.850 \longrightarrow 00:29:49.623$  by physicians.
- $430\ 00:29:53.310 \longrightarrow 00:29:55.410$  And here we come to the topic now

- $431\ 00:29:55.410 \longrightarrow 00:29:57.810$  that we want to discuss today.
- $432\ 00{:}29{:}57.810 \dashrightarrow 00{:}30{:}00.423$  There was this improvement in the control group,
- $433\ 00{:}30{:}01.530 \dashrightarrow 00{:}30{:}06.440$  and trying to interpret, the best way we can, these results.
- $434\ 00:30:06.440 \longrightarrow 00:30:10.290$  So we conducted several in-depth interviews
- $435\ 00:30:10.290 \longrightarrow 00:30:13.023$  with participants from the control group.
- 436 00:30:18.690 --> 00:30:21.723 Usually we conduct interviews
- $437\ 00:30:23.713 \longrightarrow 00:30:26.963$  with a particular focus on participants
- 438 00:30:28.017 --> 00:30:30.840 in the intervention group, you know?
- $439\ 00{:}30{:}30{:}30{:}840 \dashrightarrow 00{:}30{:}34.290$  Because we want to learn about the perceptions
- $440\ 00:30:34.290 \longrightarrow 00:30:36.090$  about the intervention,
- $441\ 00:30:36.090 \longrightarrow 00:30:40.650$  whether it was more appealing for patients or not,
- $442\ 00:30:40.650 \longrightarrow 00:30:43.503$  and things like acceptance and other topics.
- $443\ 00{:}30{:}44.550 \dashrightarrow 00{:}30{:}49.503$  We pay a lot of attention usually to the intervention group,
- $444\ 00:30:51.371 \dashrightarrow 00:30:56.371$  and we do, wrongly, less work with the control of our study.
- 445 00:30:59.010 --> 00:31:01.833 In this case, and seeing those results,
- $446\ 00:31:02.956 \longrightarrow 00:31:05.760$  we conducted these interviews,
- $447\ 00:31:05.760 \longrightarrow 00:31:08.280$  and we found that first,
- 448 00:31:08.280 --> 00:31:12.930 patients valued, really, being visited by nurses
- $449\ 00{:}31{:}12.930 \dashrightarrow 00{:}31{:}17.403$  from their clinics, from their primary care centers.
- $450\ 00:31:18.960 \longrightarrow 00:31:22.590$  They felt care, you know?
- $451\ 00{:}31{:}22.590 \dashrightarrow 00{:}31{:}26.763$  They valued that and that was something positive for them
- $452\ 00:31:26.763 \longrightarrow 00:31:29.180$  and for their own healthcare.
- $453\ 00:31:30.975 \longrightarrow 00:31:33.390$  The other thing that happened
- $454\ 00{:}31{:}33.390 \dashrightarrow > 00{:}31{:}38.390$  was that nurses provided some counseling, you know?

- $455\ 00:31:39.120 \longrightarrow 00:31:42.330\ I$  mean, they were in contact with these patients,
- $456\ 00:31:42.330 \longrightarrow 00:31:47.330$  they knew them and they provided counseling about,
- $457\ 00:31:47.610 \longrightarrow 00:31:49.860$  for example, how to get medication.
- $458\ 00{:}31{:}49.860 \dashrightarrow 00{:}31{:}54.222$  You have travel when you go to the primary care center.
- 459 00:31:54.222 --> 00:31:55.291 What can you do?
- $460\ 00:31:55.291$  --> 00:31:57.703 "I can help you with this," and comments of this kind.
- $461\ 00:31:59.451 \longrightarrow 00:32:04.451$  And the nurses did that and that's a great thing, of course,
- $462\ 00:32:04.556 \longrightarrow 00:32:08.367$  that help us understand better the results.
- $463\ 00{:}32{:}09.530$  -->  $00{:}32{:}14.530$  Patients in the control group increased the number of visits
- $464\ 00{:}32{:}14.701 \dashrightarrow 00{:}32{:}19.701$  to the clinic, for example, without any other intervention
- 465 00:32:20.220 --> 00:32:24.783 but these visits, these evaluation visits.
- $466\ 00:32:26.640 --> 00:32:29.940$  So we know all these aspects
- 467 00:32:29.940 --> 00:32:31.920 because of this qualitative approach.
- 468 00:32:31.920 --> 00:32:35.760 It was a very limited qualitative approach
- $469\ 00:32:35.760 \longrightarrow 00:32:38.813$  that we were able to do in this case,
- $470\ 00:32:40.650 --> 00:32:45.650$  but my question for you, and my reflection on that,
- $471\ 00:32:45.673 --> 00:32:50.673$  is how to better design the qualitative phase,
- 472 00:32:51.663 --> 00:32:54.930 the qualitative components of our research,
- 473 00:32:54.930 --> 00:32:56.537 to get information,
- 474 00:32:56.537 --> 00:32:59.520 not only on the intervention perceptions,
- 475 00:32:59.520 --> 00:33:01.680 the intervention group, et cetera,
- $476\ 00:33:01.680 \longrightarrow 00:33:06.680$  but also what is happening with the usual care group,
- 477 00:33:06.881 --> 00:33:09.030 or standard care group,
- $478\,00:33:09.030 --> 00:33:14.030$  and what people in this arm feel and is exposed to

- $479\ 00:33:14.340 \longrightarrow 00:33:17.670$  during the study in general.
- $480\ 00:33:17.670 \longrightarrow 00:33:18.540$  And the other thing
- 481 00:33:18.540 --> 00:33:22.143 that I was talking to Dr. Raphael yesterday
- $482\ 00:33:24.330 \longrightarrow 00:33:27.750$  was about the use of existing databases
- $483\ 00:33:27.750 \longrightarrow 00:33:32.700$  to get information about not only the control arm,
- $484\ 00:33:32.700 \longrightarrow 00:33:35.010$  but all the other centers
- $485\ 00:33:35.010 \longrightarrow 00:33:38.520$  that are a part of our target population, and therefore,
- 486 00:33:38.520 --> 00:33:40.620 not included in the study,
- $487\ 00:33:40.620 \longrightarrow 00:33:43.893$  because that would be usual care, really.
- 488 00:33:45.060 --> 00:33:47.430 And I was talking with Donna this morning,
- $489\ 00:33:47.430 \longrightarrow 00:33:52.340$  how to incorporate those things, if those data exist,
- $490\ 00:33:53.490 --> 00:33:56.280$  how to incorporate them to better understand
- $491\ 00:33:56.280 \longrightarrow 00:33:58.673$  what is usual care of centers
- 492 00:33:59.652 --> 00:34:02.852 that are not part of a clinical trial,
- $493\ 00:34:02.852 \longrightarrow 00:34:05.152$  like in this case, for example.
- $494\ 00:34:05.152 \longrightarrow 00:34:10.152$  So that's something that we can study and develop, you know,
- $495\ 00:34:13.540 \longrightarrow 00:34:16.197$  in that type of approach.
- 496~00:34:16.197 --> 00:34:18.060 We're trying to do that
- $497\ 00:34:18.060 \longrightarrow 00:34:21.465$  in another cluster-randomized controlled trial
- $498\ 00:34:21.465 --> 00:34:25.380$  that we are conducting now in Guatemala.
- $499\ 00:34:25.380 \longrightarrow 00:34:27.093$  Based on these results,
- $500~00{:}34{:}28.740 \dashrightarrow 00{:}34{:}33.427$  we started a new project with our team in Guatemala.
- $501\ 00:34:34.453 \longrightarrow 00:34:36.570$  We adapted this intervention
- $502\ 00:34:36.570 \longrightarrow 00:34:39.040$  that I presented a few minutes ago
- $503\ 00:34:42.230 --> 00:34:44.907$  to the context of Guatemala.
- $504\ 00:34:45.938 \longrightarrow 00:34:47.550$  There were a lot of adaptations,
- $505~00{:}34{:}47.550 \dashrightarrow 00{:}34{:}51.518$  and we don't have time today to go into much detail,

- $506\ 00:34:51.518 \longrightarrow 00:34:52.792$  but we designed,
- $507\ 00:34:52.792 --> 00:34:56.460$  in this cluster-randomized controlled trial in Guatemala.
- $508\ 00:34:56.460 --> 00:35:00.280$  we included 32 primary care clinics
- 509 00:35:03.663 --> 00:35:06.897 in different districts in Guatemala,
- $510~00:35:06.897 \longrightarrow 00:35:11.280$  and they were randomized to the intervention
- 511 00:35:11.280 --> 00:35:14.397 or the usual care arm of the study.
- 512 00:35:16.830 --> 00:35:19.560 And the intervention, as I said before,
- $513\ 00:35:19.560 --> 00:35:23.280$  was based on the experience in Argentina,
- $514\ 00:35:23.280 \longrightarrow 00:35:25.807$  but we did a lot of adaptations.
- $515\ 00:35:25.807 --> 00:35:27.990$  These are the final components
- $516\ 00:35:27.990 --> 00:35:31.040$  of the intervention in Guatemala.
- $517\ 00:35:31.040 --> 00:35:31.873 < v\ Donna>How was it adapted?</v>$
- $518\ 00:35:31.873 --> 00:35:34.200$  It kinds looks the same to me.
- 519 00:35:34.200 --> 00:35:36.120 <v -> I'm sorry?</v> <v -> How was it adapted,</v>
- 520 00:35:36.120 --> 00:35:39.030 because it looks very similar, or even the same,
- $521\ 00:35:39.030 \longrightarrow 00:35:41.790$  as the Argentina intervention components?
- $522\ 00:35:41.790 --> 00:35:44.040 < v -> Yes$ , there are a lot of similarities, </v>
- $523\ 00:35:44.040 \longrightarrow 00:35:46.250$  there are a lot of similarities.
- 524 00:35:46.250 --> 00:35:49.410 But for example, the mHealth component,
- 525~00:35:49.410 --> 00:35:53.820 which was text messages in Argentina, is not here,
- 526 00:35:53.820 --> 00:35:55.950 is not part of the trial in Guatemala,
- $527\ 00{:}35{:}55{.}950 \dashrightarrow 00{:}36{:}00.897$  because of the very high proportion of illiteracy
- 528 00:36:02.040 --> 00:36:03.690 in Guatemala.
- 529 00:36:03.690 --> 00:36:06.960 So there is a high proportion of people
- 530 00:36:06.960 --> 00:36:11.070 who cannot read and write,
- $531\ 00:36:11.070 \longrightarrow 00:36:16.070$  so we did a lot of work trying to adapt, with visual aids,
- $532\ 00:36:17.554 \longrightarrow 00:36:20.721$  the messages, but we didn't find a way

- $533\ 00:36:23.379 \longrightarrow 00:36:25.511$  to make it feasible here,
- $534\ 00:36:25.511 \longrightarrow 00:36:28.178$  so that's not part of the trial.
- $535\ 00:36:29.507 \longrightarrow 00:36:34.507$  There, home blood pressure monitoring is quite the same.
- 536 00:36:34.680 --> 00:36:37.820 What we adapted here is the training,
- 537 00:36:40.427 --> 00:36:42.300 or the education of patients,
- $538\ 00:36:42.300 \longrightarrow 00:36:44.760$  on how to use these devices,
- $539\ 00:36:44.760 \longrightarrow 00:36:46.350$  again, for the same reason.
- 540 00:36:46.350 --> 00:36:51.030 So we used pictures, for example, for patients
- 541 00:36:51.030 --> 00:36:54.965 and we did a lot of training with the patient,
- $542\ 00:36:54.965$  --> 00:36:59.965 just to be sure that they were able to use those devices.
- $543\ 00:37:02.628$  --> 00:37:06.870 And here, about the team collaborative approach,
- $544\ 00:37:06.870 \longrightarrow 00:37:11.870$  in Guatemala, the system is organized in a different way,
- 545 00:37:12.164 --> 00:37:14.940 compared to Argentina,
- $546\ 00:37:14.940 \longrightarrow 00:37:17.913$  so we have to work with more levels.
- $547\ 00:37:19.650 --> 00:37:24.123$  For example, in this clinic, there is no doctor.
- 548 00:37:25.443 --> 00:37:28.803 In Argentina, each primary care clinic
- $549\ 00:37:28.803 --> 00:37:33.210$  has a primary care team with at least a doctor,
- $550\ 00:37:33.210 --> 00:37:36.390$  in general, a general practitioner,
- 551 00:37:36.390 --> 00:37:39.120 one nurse and one community health worker.
- 552 00:37:39.120 --> 00:37:41.243 That's more or less a rule,
- $553\ 00{:}37{:}41.243 \dashrightarrow 00{:}37{:}46.243$  and in some clinics there are more people and more doctors
- $554\ 00:37:47.460 --> 00:37:50.523$  or nurses or community health workers.
- 555 00:37:50.523 --> 00:37:52.930 In Guatemala, in each clinic,
- 556 00:37:52.930 --> 00:37:57.060 there is one auxiliary nurse at least,
- $557~00{:}37{:}57.060 \dashrightarrow 00{:}38{:}01.173$  and maybe that's the only personnel at the clinic.
- 558 00:38:02.190 --> 00:38:06.600 In the higher level of clinics,
- $559\ 00:38:06.600 \longrightarrow 00:38:08.317$  they have also a nurse,

 $560\ 00:38:09.971$  --> 00:38:14.253 and then they have centers where they have doctors.

561 00:38:15.510 --> 00:38:18.810 These are interconnected,

 $562\ 00:38:18.810 \longrightarrow 00:38:22.099$  but you have to work with these different pieces.

 $563~00{:}38{:}22.099 \dashrightarrow 00{:}38{:}26.652$  So this collaborative team approach was different

 $564\ 00:38:26.652 \longrightarrow 00:38:29.527$  as the ones in Argentina.

 $565\ 00:38:29.527$  --> 00:38:33.944 A lot of other things are very similar, very similar.

 $566\ 00:38:35.551 --> 00:38:38.943$  So this is the intervention in Guatemala.

 $567\ 00:38:38.943 \longrightarrow 00:38:43.943$  In Guatemala, and this maybe is a topic for another meeting,

 $568\ 00:38:46.260 \longrightarrow 00:38:48.930$  we have other types of challenges

 $569\ 00:38:48.930 \longrightarrow 00:38:53.930$  connected with the different ethnic groups.

 $570~00:38:54.450 \longrightarrow 00:38:59.450$  In Guatemala, there are many different populations,

 $571~00{:}39{:}01.080 \dashrightarrow 00{:}39{:}06.080$  that, for example, some of them speak Spanish,

 $572\ 00:39:06.717 \longrightarrow 00:39:08.790$  some of them are bilingual,

 $573\ 00:39:08.790 --> 00:39:13.290$  so they speak Spanish and a Mayan language,

 $574\ 00:39:13.290 --> 00:39:17.670$  and some of them speak only in Mayan languages,

 $575\ 00:39:17.670$  --> 00:39:22.670 and some Mayan languages have a written form and others not.

 $576\ 00:39:24.570 \dashrightarrow 00:39:29.570$  So there we have another very, very challenging situation

 $577\ 00:39:31.601 --> 00:39:34.270$  and we work a lot with the materials

 $578\ 00:39:35.280 \longrightarrow 00:39:38.767$  and according to these different populations.

579 00:39:38.767 --> 00:39:43.767 (participants speaking in foreign language)

580~00:39:55.064 --> 00:40:00.064 (participants speaking in foreign language continues)

 $581\ 00:40:08.443 --> 00:40:13.350$  Okay, so well, this is study in Guatemala

 $582\ 00:40:15.059 \longrightarrow 00:40:18.123$  and the field work.

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583\ 00:40:20.220 --> 00:40:22.401 Equity, this is another topic. (laughs)
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- $584\ 00:40:22.401 \longrightarrow 00:40:23.763$  This is another big topic.
- $585\ 00:40:30.150 --> 00:40:35.040$  So what's the state of the study in Guatemala?
- $586\ 00:40:35.040 \longrightarrow 00:40:38.553$  We finished the field work last week,
- $587\ 00:40:39.810 --> 00:40:43.980$  so we are just starting cleaning the database
- $588\ 00:40:43.980 \longrightarrow 00:40:46.770$  and preparing it for analysis.
- 589 00:40:46.770 --> 00:40:49.470 We will have the results in a few months,
- $590\ 00:40:49.470 --> 00:40:53.599$  so we can share those results with you,
- 591 00:40:53.599 --> 00:40:58.599 but what I'd like to share here,
- $592\ 00:41:00.540 \longrightarrow 00:41:02.217$  in terms of the control group
- 593 00:41:02.217 --> 00:41:04.590 and how to approach the control group,
- 594 00:41:04.590 --> 00:41:09.450 is based on our learnings from Argentina,
- 595 00:41:09.450 --> 00:41:12.420 from the design phase of the study
- 596 00:41:12.420 --> 00:41:16.200 planned for different evaluations,
- 597 00:41:16.200 --> 00:41:19.857 not only of the control arm of the trial,
- $598\ 00:41:19.857 --> 00:41:24.857$  but also on other clinical posts and centers
- 599 00:41:25.380 --> 00:41:27.510 that were not included in the study,
- $600~00{:}41{:}27.510 \dashrightarrow 00{:}41{:}32.510$  so I hope we have more data to evaluate this usual care
- $601\ 00:41:32.976 \longrightarrow 00:41:35.059$  at the end of this study.
- $602\ 00:41:36.030 --> 00:41:38.790$  And this has also budget implications.
- 603 00:41:38.790 --> 00:41:40.260 So for us researchers.
- $604\ 00:41:40.260 \longrightarrow 00:41:42.540$  it is important to have that in mind
- $605\ 00:41:42.540 \longrightarrow 00:41:43.630$  and plan in advance,
- 606 00:41:44.910 --> 00:41:47.730 because it's different, it's really difficult,
- 607 00:41:47.730 --> 00:41:49.620 in particular if,
- $608\ 00:41:49.620 \longrightarrow 00:41:54.093$  as it happens in Guatemala and in many other countries,
- 609 00:41:55.410 --> 00:41:58.317 information is not so easily obtained,
- $610\ 00:41:58.317 --> 00:42:02.850$  and it's not so easy to access this information
- $611\ 00:42:02.850 \longrightarrow 00:42:04.380$  from other centers.

- $612\ 00:42:04.380 \longrightarrow 00:42:07.537$  So there is a lot of work there as well.
- $613\ 00:42:07.537 \longrightarrow 00:42:12.537$  So that's what I'd like to share with you
- 614 00:42:14.760 --> 00:42:17.730 and to put on the table, you know?
- $615~00:42:17.730 \longrightarrow 00:42:22.730$  What can we do as researchers to improve our study
- $616\ 00{:}42{:}23.349 \dashrightarrow 00{:}42{:}24.182$  and evaluation of the so-called usual care in our studies.
- $617\ 00:42:30.424 \longrightarrow 00:42:31.753 \text{ Yes?} < v \longrightarrow \text{That was a wonderful talk.} < /v >$
- $618~00{:}42{:}31.753 \dashrightarrow 00{:}42{:}35.130$  You talked a little bit with the first study in Argentina
- $619\ 00:42:35.130 \longrightarrow 00:42:36.660$  about some of your hypotheses
- $620\ 00:42:36.660 --> 00:42:38.730$  about the improvement in the control group
- $621\ 00:42:38.730 --> 00:42:42.210$  with regards to these individuals making house visits.
- $622\ 00:42:42.210$  --> 00:42:46.050 I was also interested in to what degree, in either study,
- $623\ 00:42:46.050 \longrightarrow 00:42:48.630$  there might be cluster-level differences
- $624\ 00:42:48.630 \longrightarrow 00:42:52.020$  between the different clinics that you're randomizing,
- $625\ 00:42:52.020 \longrightarrow 00:42:56.100$  and whether you account for those when you do randomization,
- $626\ 00:42:56.100 --> 00:42:59.403$  say by stratified randomization or restricted randomization,
- $627\ 00:43:01.470 \longrightarrow 00:43:02.730$  if you think those factors
- $628\ 00:43:02.730$  --> 00:43:07.730 might lead to systematic differences between the two groups?
- $629~00{:}43{:}07.980 \dashrightarrow 00{:}43{:}09.630$  That's something that I've struggled a lot with
- $630~00{:}43{:}09.630 \dashrightarrow 00{:}43{:}12.053$  in my research and I'm curious how you think about it.
- $631\ 00:43:13.290 \longrightarrow 00:43:14.520 < v \longrightarrow That's a great question. < / v >$
- $632\ 00:43:14.520 \longrightarrow 00:43:16.723$  We struggled (laughs) a lot as well.
- $633\ 00:43:16.723 \longrightarrow 00:43:20.790$  We have eligibility criteria for the individuals,
- 634 00:43:20.790 --> 00:43:23.250 I showed you those criteria,

- 635 00:43:23.250 --> 00:43:26.276 but also for the clinics, trying to, you know,
- 636 00:43:26.276 --> 00:43:28.110 have a set of...
- $637\ 00{:}43{:}28.110 --> 00{:}43{:}32.010$  I mean, trying to reduce variability between the clinics
- $638\ 00:43:32.010 \longrightarrow 00:43:35.670$  that we invited to participate in the study.
- $639\ 00:43:35.670 \longrightarrow 00:43:37.563$  So that was one thing,
- $640\ 00:43:38.730 \longrightarrow 00:43:42.243$  in terms of resources, size, et cetera.
- $641\ 00:43:43.530 \longrightarrow 00:43:47.536$  The other thing is that we live in a federal country,
- 642 00:43:47.536 --> 00:43:50.253 so each province in our country, in Argentina,
- $643\ 00:43:51.750 \longrightarrow 00:43:56.743$  has their own rules, regulations
- $644\ 00{:}43{:}57.797 \dashrightarrow 00{:}44{:}02.137$  and let's say, organization of the health care system.
- $645\ 00{:}44{:}03.210$  -->  $00{:}44{:}06.047$  So yeah, we were working with several provinces
- $646\ 00{:}44{:}06.047 \dashrightarrow 00{:}44{:}09.830$  in the country, so we stratified by province, for example,
- $647\ 00:44:09.830 \longrightarrow 00:44:12.870$  to take into account that,
- $648\ 00:44:12.870 \longrightarrow 00:44:15.537$  to try to adjust for that variable.
- $649\ 00{:}44{:}17.716 \dashrightarrow 00{:}44{:}22.049$  And there was no other stratification in this trial.
- $650\ 00:44:23.100 \longrightarrow 00:44:26.536$  We tried to manage variability
- $651\ 00:44:26.536 \longrightarrow 00:44:31.230$  through this eligibility criteria, in terms of...
- 652 00:44:31.230 --> 00:44:33.390 I don't remember exactly,
- $653\ 00:44:33.390 --> 00:44:37.350$  I think it was three or four variables,
- $654\ 00:44:37.350 \longrightarrow 00:44:39.053$  factors we took into account.
- $655\ 00:44:39.053 \longrightarrow 00:44:40.983$  One was size of the clinic,
- $656\ 00:44:44.688 --> 00:44:45.573$  the composition of the primary care team in each clinic,
- 657 00:44:49.740 --> 00:44:53.280 not to mix, you know, maybe big clinics
- $658\ 00:44:53.280 \longrightarrow 00:44:56.010$  with a lot of personnel,
- $659\ 00:44:56.010 \longrightarrow 00:44:59.579$  versus other ones that were smaller,
- $660\ 00:44:59.579 \longrightarrow 00:45:02.523$  so we took that in account,

- $661\ 00{:}45{:}03.570 {\:{\mbox{--}}}{>}\ 00{:}45{:}08.570$  provision of medication, because although medication
- 662 00:45:09.600 --> 00:45:13.470 is provided for free in our country,
- $663\ 00:45:13.470 --> 00:45:17.790$  for people who has only public insurance,
- $664\ 00{:}45{:}17.790 \dashrightarrow 00{:}45{:}21.783$  only public insurance and not other type of coverage,
- $665\ 00:45:22.964 \longrightarrow 00:45:27.946$  the quantity and delivery of medication is different
- $666\ 00:45:27.946 \longrightarrow 00:45:32.946$  from different clinics or districts within each product.
- $667\ 00:45:33.570 \longrightarrow 00:45:36.420$  So we took that in account as well.
- $668\ 00{:}45{:}36.420 \dashrightarrow 00{:}45{:}40.337$  That was another way of trying to balance clinics
- $669\ 00:45:42.540 \longrightarrow 00:45:44.610$  before randomization.
- $670\ 00:45:45.668 \longrightarrow 00:45:48.985$  And after that, it was simple randomization of clinics,
- 671 00:45:48.985 --> 00:45:52.590 stratified by province and no more than that.
- 672 00:45:52.590 --> 00:45:55.110 But I agree with you, I agree with you.
- $673~00{:}45{:}55.110 \dashrightarrow 00{:}46{:}00.110$  It may be for sure something that could have influence
- $674\ 00:46:02.611 \longrightarrow 00:46:05.528$  in these differences that we found.
- 675 00:46:08.504 --> 00:46:09.720 It's always difficult.
- 676 00:46:09.720 --> 00:46:11.250 In implementation research,
- 677 00:46:11.250 --> 00:46:12.983 you know that it's always difficult,
- $678\ 00:46:12.983 \longrightarrow 00:46:15.540$  this balance and this trade-off,
- 679 00:46:15.540 --> 00:46:20.540 between what is feasible and what we,
- $680\ 00:46:20.933 --> 00:46:25.535$  from a design point of view, want for our trial.
- $681\ 00:46:25.535 \longrightarrow 00:46:27.452$  It's difficult, really.
- 682 00:46:28.470 --> 00:46:31.380 <<br/>v Donna> One suggestion on a statistical level<br/></v>
- 683 00:46:31.380 --> 00:46:34.710 for this issue would be secondary analysis,
- $684\ 00:46:34.710 --> 00:46:37.680$  where you control for baseline patient
- 685 00:46:37.680 --> 00:46:40.380 and clinical-level characteristics,

- $686\ 00:46:40.380 \longrightarrow 00:46:43.083$  and then see how that changes the contrast.
- $687\ 00:46:44.520 \longrightarrow 00:46:46.170 < v \longrightarrow That's a great subject. < / v >$
- $688\ 00:46:46.170 \longrightarrow 00:46:48.176$  Yes, we explore.
- 689 00:46:48.176 --> 00:46:50.734 <v -> Yeah, exactly.</v> <v -> We explored that,</v>
- $690\ 00:46:50.734 \longrightarrow 00:46:53.567$  and we didn't find any difference.
- 691 00:47:00.480 --> 00:47:02.970 We didn't have much data, you know,
- $692\ 00:47:02.970 \longrightarrow 00:47:04.420$  just in terms of the clinics,
- $693\ 00:47:06.180 \longrightarrow 00:47:09.450$  but we did exploration about that.
- 694 00:47:09.450 --> 00:47:13.653 We didn't find differences in the results.
- $695~00{:}47{:}18.570 \dashrightarrow 00{:}47{:}22.570$  So that's something that I proposed to work on
- $696\ 00:47:22.570 \longrightarrow 00:47:24.300$  in the future.
- 697 00:47:24.300 --> 00:47:25.773 <v Donna>I'm curious, Vilma,</v>
- $698\ 00{:}47{:}28.140$  -->  $00{:}47{:}32.430$  has the TREIN/HyTREC consortium discussed this issue at all?
- $699\ 00{:}47{:}32.430 \dashrightarrow 00{:}47{:}36.120$  Have the other projects also seen the same sort of,
- $700\ 00:47:36.120 --> 00:47:39.270$  maybe not necessarily in the same magnitude,
- 701 00:47:39.270 --> 00:47:43.860 but the direction of improvements in control groups?
- 702 00:47:43.860 --> 00:47:46.230 Like, was it a consortium-wide phenomena?
- $703\ 00:47:46.230 \longrightarrow 00:47:47.063$  Do we know?
- 704 00:47:48.300 --> 00:47:53.300 <<br/>v ->No, I don't know, but it hasn't been discussed yet.</br/>/v>
- 705 00:47:53.760 --> 00:47:57.210 We have a meeting in September, I think,
- $706\ 00:47:57.210 \longrightarrow 00:48:01.470$  and our idea is to share these results
- $707\ 00:48:01.470 \longrightarrow 00:48:03.330$  and see what is happening
- $708\ 00:48:03.330 \longrightarrow 00:48:05.667$  in other studies in the consortium,
- $709\ 00:48:05.667 --> 00:48:08.013$  but it hasn't been discussed yet.
- 710 00:48:09.750 --> 00:48:12.510 <<br/>v Donna>I know we've seen a similar phenomena</br/>/v>
- 711 00:48:12.510 --> 00:48:14.610 in our work site intervention studies,

- $712\ 00:48:14.610 --> 00:48:17.130$  where we're trying to improve food
- $713\ 00:48:17.130 \longrightarrow 00:48:19.980$  and physical activity environment at work sites,
- 714 00:48:19.980 --> 00:48:23.040 to reduce cardiometabolic risk,
- $715\ 00:48:23.040 \longrightarrow 00:48:26.446$  and then we find, just simply by screening
- 716 00:48:26.446 --> 00:48:28.770 and then waiting six months,
- $717\ 00:48:28.770 \longrightarrow 00:48:31.770$  we see big improvements in blood pressure
- 718 00:48:31.770 --> 00:48:35.370 and smaller ones in blood sugar and so forth,
- $719\ 00:48:35.370 \longrightarrow 00:48:36.750$  which I think has been seen.
- $720\ 00:48:36.750 \longrightarrow 00:48:40.170$  Like, screening itself is a public health intervention,
- 721 00:48:40.170 --> 00:48:43.680 but I've also read it's not a durable one,
- $722\ 00:48:43.680 \longrightarrow 00:48:45.990$  without additional supports.
- $723\ 00:48:45.990 --> 00:48:47.640$  So you might see some additional...
- 724 00:48:47.640 --> 00:48:50.340 People may improve when they find out,
- 725 00:48:50.340 --> 00:48:52.470 but then, they'll go back, maybe,
- $726\ 00:48:52.470 \longrightarrow 00:48:54.120$  if we don't have these other things.
- $727\ 00:48:54.120 \longrightarrow 00:48:55.159$  So there's maybe short-term...
- 728~00:48:55.159 --> 00:48:59.730 Like, would the short-term improvements in the control group
- 729 00:48:59.730 --> 00:49:03.720 be sustainable, say for two years or five years,
- $730\ 00:49:03.720 \longrightarrow 00:49:05.190$  or would they start to go away,
- $731\ 00:49:05.190 \longrightarrow 00:49:07.290$  whereas the intervention group
- $732\ 00:49:07.290 \longrightarrow 00:49:09.120$  can maintain their improvements
- $733\ 00:49:09.120 \longrightarrow 00:49:12.390$  and maybe even continue to improve?
- 734 00:49:12.390 --> 00:49:13.230 <v ->I agree.</v>
- 735 00:49:13.230 --> 00:49:16.440 I fully agree and I think that...
- $736~00{:}49{:}16.440 \dashrightarrow 00{:}49{:}21.440$  Actually, we prepare a proposal to measure sustainability
- 737 00:49:22.110 --> 00:49:26.241 of the resource in Argentina and we didn't make it,
- 738 00:49:26.241 --> 00:49:29.130 but I think that that's something

- $739\ 00:49:29.130 --> 00:49:32.883$  to talk with funders about, you know?
- $740\ 00:49:33.840 \longrightarrow 00:49:36.630$  Because there is a lot of effort and resources
- 741 00:49:36.630 --> 00:49:40.560 put in each of these trials that we conduct,
- $742\ 00:49:40.560$  --> 00:49:45.560 and we don't know, in general, what happened half the time.
- $743\ 00:49:46.770 --> 00:49:49.890$  I have some data about this trial in particular,
- $744\ 00{:}49{:}49.890 \dashrightarrow 00{:}49{:}54.890$  because this program was adopted by one of the provinces
- 745 00:49:56.400 --> 00:50:00.694 and it was scaled up through the province,
- 746 00:50:00.694 --> 00:50:04.083 one of the province that I showed in the first map.
- 747 00:50:05.370 --> 00:50:08.040 So I have data on that,
- $748\ 00:50:08.040 \longrightarrow 00:50:12.993$  and they are very, very successful.
- 749 00:50:14.070 --> 00:50:15.237 That's good data.
- $750\ 00:50:16.110 --> 00:50:19.387$  The difference is not so big as in the trial,
- 751 00:50:19.387 --> 00:50:22.220 as usual, but they keep improving.
- $752\ 00:50:23.109$  -->  $00:50:25.617\ \mathrm{I}$  don't know what happens in the other provinces,
- 753 00:50:25.617 --> 00:50:28.620 but I think that's something that would be really great
- $754\ 00:50:28.620 \longrightarrow 00:50:30.180$  if we can do that.
- 755 00:50:30.180 --> 00:50:31.838 In terms of the time,
- 756 00:50:31.838 --> 00:50:35.250 I mean, the timeline of our project,
- $757\ 00:50:35.250 \longrightarrow 00:50:38.190$  in general, we cannot do that.
- 758 00:50:38.190 --> 00:50:43.190 So it's time budget, but I think it would be great
- 759 00:50:44.622 --> 00:50:47.490 if, really, it's possible now,
- $760\ 00:50:47.490 \longrightarrow 00:50:49.473$  to see what happened with these.
- 761 00:50:51.000 --> 00:50:53.640 These programs, these projects,
- $762\ 00:50:53.640 --> 00:50:56.910$  are adopted by the government.
- 763 00:50:56.910 --> 00:51:01.320 You have data afterwards, but if not,
- $764\ 00{:}51{:}01.320 {\:{\mbox{--}}\!>\:} 00{:}51{:}05.193$  in general, it's difficult to know what happened.

765 00:51:08.688 --> 00:51:11.588 <-v Donna>How did the randomization work out in Guatemala?</v>

766 00:51:12.720 --> 00:51:15.180 <v -> In terms of the clinic?</v> <v -> Of the balance?</v>

767 00:51:15.180 --> 00:51:18.929 Yeah, like, in table one, like you showed us-

768 00:51:18.929 --> 00:51:19.893 <-> Yeah.</v> <-> And did you</v>

 $769\ 00:51:19.893 \longrightarrow 00:51:21.810$  have significant differences between-

770 00:51:21.810 --> 00:51:22.643 < v -> No. </ v > < v -> Oh, good. </ v >

771 00:51:22.643 --> 00:51:24.427 < v -> No, it was better. (laughs)< / v >

772 00:51:24.427 --> 00:51:25.893 In that sense, it was better. (Donna laughing)

774 00:51:27.930 --> 00:51:30.134 <v ->Yeah, and I don't have the table now,</v>

 $775\ 00:51:30.134 --> 00:51:32.117$  but in Guatemala, it was more balanced.

776 00:51:32.117 --> 00:51:33.060 <v Donna>Uh-huh.</v>

777 00:51:33.060 --> 00:51:33.893 <v -> Yeah.</v>

778 00:51:36.150 --> 00:51:37.920 <v Donna>So I'm monitoring the chat,</v>

 $779\ 00:51:37.920 --> 00:51:40.933$  and it seems that people are being a little shy.

780 00:51:40.933 --> 00:51:42.486 <v ->Oh, I have another question.</v> <v ->Oh, good.</v>

781 00:51:42.486 --> 00:51:43.380 (attendees laughing) I have some too,

782 00:51:43.380 --> 00:51:46.193 but I didn't wanna hog the whole discussion.

783 00:51:46.193 --> 00:51:48.990 <v Attendee>So do you know to what degree</v>

 $784~00{:}51{:}48.990 \dashrightarrow 00{:}51{:}51.780$  the interventions worked in the intervention arm?

 $785\ 00{:}51{:}51.780 \dashrightarrow 00{:}51{:}56.780$  Because I'm just wondering, A, how successful they were,

 $786\ 00:51:57.270 --> 00:51:58.680$  or B, if there were other factors

 $787\ 00:51:58.680 \longrightarrow 00:52:00.420$  that restricted the ability to improve?

788 00:52:00.420 --> 00:52:04.290 For example, you were mentioning about a lack of medications

 $789\ 00:52:04.290 \longrightarrow 00:52:05.490$  in the health facilities.

 $790\ 00:52:05.490 --> 00:52:07.350\ I$  can imagine that no matter what you do

791 00:52:07.350  $\rightarrow$  00:52:09.060 with all those interventions, if there aren't drugs,

792 00:52:09.060 --> 00:52:11.220 things might not get better.

 $793\ 00:52:11.220 \longrightarrow 00:52:13.470$  Do you have any information on the fidelity, basically,

 $794\ 00:52:13.470 \longrightarrow 00:52:14.790$  of the intervention.

 $795\ 00:52:14.790 \longrightarrow 00:52:18.000$  or factors that might have impeded the fidelity?

 $796\ 00:52:18.000 \longrightarrow 00:52:19.580 < v \longrightarrow Yes$ , we have...</v>

797 00:52:22.423 --> 00:52:26.727 We have quite a lot of information from the Argentina trial.

798 00:52:28.170 --> 00:52:30.480 But there is something I would like to comment

 $799\ 00:52:30.480 \longrightarrow 00:52:33.217$  connected with your question in Guatemala.

800 00:52:34.072 --> 00:52:39.072 In Guatemala, the Ministry of Health

801 00:52:39.180 --> 00:52:41.940 was part of the trial, of the project,

802 00:52:41.940 --> 00:52:44.070 from the very beginning.

 $803\ 00:52:44.070 \longrightarrow 00:52:47.900$  They were involved in the design of the intervention,

 $804\ 00:52:47.900 \longrightarrow 00:52:49.950$  in the monitoring of the intervention,

 $805\ 00:52:49.950 \longrightarrow 00:52:52.683$  so they were very much involved.

 $806\ 00:52:53.910 \longrightarrow 00:52:58.582$  And they committed themself to assure

 $807~00{:}52{:}58.582 \dashrightarrow 00{:}53{:}03.582$  that there would be medication at the health posts

 $808\ 00:53:06.782 \longrightarrow 00:53:11.087$  at least during the trial or duration of the trial.

 $809\ 00:53:11.087 \longrightarrow 00:53:13.078$  And they did it.

810 00:53:13.078 --> 00:53:14.729 With some periods, you know,

811 00:53:14.729 --> 00:53:17.600 that they have problems, limitations,

812 00:53:17.600 --> 00:53:21.130 shortage of medication, but they did it,

 $813\ 00:53:21.130 \longrightarrow 00:53:25.110$  and they work a lot to provide medication

 $814\ 00:53:25.110 \longrightarrow 00:53:30.110$  and to prioritize these centers, part of the study,

- $815\ 00:53:30.360 \longrightarrow 00:53:32.753$  in the provision of medication.
- $816\ 00:53:34.620 \longrightarrow 00:53:37.890$  So something that we...
- 817 00:53:37.890 --> 00:53:42.890 Again, I don't have the data to talk about,
- $818\ 00:53:44.546 \longrightarrow 00:53:49.546$  but we know that there was improvement
- $819\ 00:53:51.780 \longrightarrow 00:53:53.490$  in both arms in Guatemala,
- $820\ 00:53:53.490 \longrightarrow 00:53:56.403$  something similar to what happened in Argentina,
- 821 00:53:57.570 --> 00:54:00.000 and through qualitative interviews,
- $822\ 00:54:00.000 --> 00:54:03.080$  we understood that people was really very...
- 823 00:54:06.810 --> 00:54:09.284 I mean, they felt very well,
- $824\ 00{:}54{:}09.284 \dashrightarrow 00{:}54{:}14.040$  because they noticed that there were medication
- $825\ 00:54:14.040 \longrightarrow 00:54:16.873$  at the centers, where in the past,
- $826\ 00:54:17.820 \longrightarrow 00:54:22.140$  maybe they have much more problem to get those medicines.
- $827\ 00:54:22.140$  --> 00:54:25.180 That's something that all the participants said.
- 828 00:54:27.284 --> 00:54:31.034 So a very basic thing like having medication,
- $829\ 00:54:31.950 \longrightarrow 00:54:33.930$  access to medication, in the centers,
- 830 00:54:33.930 --> 00:54:38.930 that was something that was more or less assured
- 831 00:54:39.060 --> 00:54:40.773 in both arms of the study.
- 832 00:54:42.330  $\rightarrow$  00:54:47.330 But in our approach to the other centers in Guatemala,
- $833\ 00:54:47.383 \longrightarrow 00:54:51.303$  same district, same district, but not part of the study,
- $834\ 00:54:52.506 \longrightarrow 00:54:57.360$  we are collecting information about medication,
- $835\ 00:54:57.360 \longrightarrow 00:55:01.553$  and the lack of medication is very important.
- 836 00:55:03.900 --> 00:55:06.099 There were serious problems,
- $837\ 00:55:06.099 \dashrightarrow 00:55:09.049$  serious problems with the provision of medication
- 838 00:55:09.049 --> 00:55:13.530 in all the other centers in the same district,
- 839 00:55:13.530 --> 00:55:15.293 different to the centers in the study.

 $840\ 00:55:20.520 \longrightarrow 00:55:24.120$  So that's something that if you cannot assure that,

841 00:55:24.120 --> 00:55:26.940 I mean, if you cannot provide medication,

 $842\ 00:55:26.940 \longrightarrow 00:55:30.960$  as you said, whatever you do with the other alternatives,

 $843\ 00:55:30.960 \longrightarrow 00:55:34.950$  that is just maybe useless.

844 00:55:34.950 --> 00:55:37.440 <v Donna>And was this in Argentina you're talking about?</v>

845 00:55:37.440 --> 00:55:39.488 Or Guatemala?  $\langle v - \rangle$ Guatemala. $\langle /v \rangle$ 

 $847\ 00:55:42.630 --> 00:55:47.000$  In this case, Guatemala, because in the preparation phase,

848 00:55:47.000 --> 00:55:49.980 in the pre-implementation phase of the study,

849 00:55:49.980 --> 00:55:54.030 we did a lot of research about what is happening

 $850\ 00:55:54.030 \longrightarrow 00:55:57.537$  with the availability of drugs in the centers,

 $851\ 00:55:57.537 --> 00:56:00.960$  and we found that there were big problems there.

852 00:56:00.960 --> 00:56:04.170 So we talk with the Ministry of Health,

 $853\ 00:56:04.170 \longrightarrow 00:56:09.170$  they committed to work on that for these centers,

 $854\ 00:56:09.540 \longrightarrow 00:56:11.613$  for these clinics, and they did.

 $855\ 00:56:12.870 --> 00:56:17.697$  But the rest, again, the usual care in reality in Guatemala

 $856\ 00:56:19.898 \longrightarrow 00:56:20.820$  was different.

857 00:56:20.820 --> 00:56:23.750 I don't know how much impact this will have

 $858\ 00:56:23.750 \longrightarrow 00:56:25.323$  on this trial yet.

 $859\ 00:56:26.474 \longrightarrow 00:56:28.410$  But it happened there.

860 00:56:28.410 --> 00:56:29.610 <v Donna>So Vilma, we've gotten...</v>

861 00:56:29.610 --> 00:56:32.220 It's like three questions now on the chat,

862 00:56:32.220 --> 00:56:35.250 and we only have two or three minutes,

 $863\ 00:56:35.250 \longrightarrow 00:56:36.770$  so what I thought I might do

 $864\ 00:56:36.770 \longrightarrow 00:56:39.270$  is just ask all of them in four minutes,

 $865\ 00:56:39.270 \longrightarrow 00:56:41.280$  I'd ask all of the questions,

 $866~00{:}56{:}41.280 \dashrightarrow 00{:}56{:}44.160$  and maybe you can just try to address them together?

867 00:56:44.160 --> 00:56:49.057 <-> Yes.</v> <-> So John Roman asked,</v>

868 00:56:49.057 --> 00:56:50.760 "Was there any incentives given

869 00:56:50.760 --> 00:56:52.950 to either participants or care providers?"

870 00:56:52.950 --> 00:56:55.209 I think he means financial incentives-

871 00:56:55.209 --> 00:56:57.545 < v -> No, (laughs) a short question.</v>

872 00:56:57.545 --> 00:56:59.790 < v ->Okay, good-</v> < v ->A short answer. (laughs)</v>

873 00:56:59.790 --> 00:57:01.717 <v Donna>Oh, Raphael Perez Escamilla asked,</v>

874 00:57:01.717 --> 00:57:05.070 "Was text messaging used in Argentina and Guatemala

 $875\ 00:57:05.070 \longrightarrow 00:57:06.330$  as part of the intervention?

876 00:57:06.330 --> 00:57:07.770 If so, was it helpful?"

877 00:57:07.770 --> 00:57:09.960 You've actually addressed that a little bit,

 $878\ 00:57:09.960 \longrightarrow 00:57:12.030$  but maybe if there was data on...

879 00:57:12.030 --> 00:57:14.820 So Raphael, it wasn't used in Guatemala,

880 00:57:14.820 --> 00:57:16.920 because of the literacy issues,

881 00:57:16.920 --> 00:57:18.750 but in Argentina it was used,

882 00:57:18.750 --> 00:57:20.070 and I don't know, Vilma,

 $883\ 00:57:20.070 --> 00:57:23.760$  if there was any way to independently look at that component

 $884\ 00:57:23.760 \longrightarrow 00:57:25.230$  to see how helpful it was,

 $885\ 00{:}57{:}25.230 \dashrightarrow 00{:}57{:}29.220$  compared to all these other complex components?

886 00:57:29.220 --> 00:57:31.770 < v -> No, it's difficult to separate <math></v>

 $887\ 00:57:31.770 --> 00:57:34.890$  and to analyze independently the contribution.

888 00:57:34.890 --> 00:57:37.230 But there was a high correlation

 $889\ 00:57:37.230 \longrightarrow 00:57:40.890$  with the dose received of text messages

- $890\ 00:57:40.890 \longrightarrow 00:57:42.320$  and the blood pressure control.
- $892\ 00:57:45.000 \longrightarrow 00:57:46.500$  that can be interpreted
- $893\ 00:57:46.500 \longrightarrow 00:57:51.097$  as these were a useful part of the intervention.
- 894 00:57:52.546 --> 00:57:53.379 <v Donna>Oh, good.</v>
- 895 00:57:53.379 --> 00:57:55.207 And then Anna Julio asked,
- 896 00:57:55.207 --> 00:57:57.840 "How sustainable is the intervention?
- 897  $00:57:57.840 \longrightarrow 00:58:00.750$  Was it adopted by the Ministry of Health in total?
- 898~00:58:00.750 --> 00:58:03.990 Besides the medications, the mHealth component?"
- $899\ 00:58:03.990 \longrightarrow 00:58:06.030$  So I think you've discussed that a little bit
- 900~00:58:06.030 --> 00:58:10.590 maybe about Guatemala, but not so much for Argentina.
- 901 00:58:10.590 --> 00:58:12.900 <v -> In Argentina, the intervention was adopted </v>
- 902 00:58:12.900 --> 00:58:14.280 by only one province.
- 903 00:58:14.280 --> 00:58:16.163 <v Donna>Oh, that's right, you did say that.</v>
- 904 00:58:18.540 --> 00:58:19.800 <v -> And it's working. (laughs)</v>
- 905 00:58:19.800 --> 00:58:21.510 It's working, you know?
- 906 00:58:21.510 --> 00:58:23.910 But not in the other provinces.
- $907\ 00:58:23.910$  --> 00:58:28.910 And shortly, this is the base for the HEARTS initiative.
- 908 00:58:29.220 --> 00:58:31.397 The HEARTS Initiative in the Americas,
- 909 00:58:31.397 --> 00:58:34.110 in the case of Argentina,
- $910\ 00:58:34.110 \longrightarrow 00:58:36.420$  was built on this intervention.
- 911 00:58:36.420 --> 00:58:40.230 So we could contribute, you know,
- $912\ 00:58:40.230 --> 00:58:42.330$  with many implementation indicators
- 913 00:58:42.330 --> 00:58:45.660 for them to implement the initiative.
- 914 00:58:45.660 --> 00:58:46.943 That's something, not much, but something.

- 915 00:58:48.857 --> 00:58:51.180 <v Donna>Vilma, maybe like in your remaining few minutes</v>
- 916 00:58:51.180 --> 00:58:53.867 you could say a little bit more about the HEARTS Initiative,
- 917 00:58:53.867 --> 00:58:56.130 'cause a number of us, myself included,
- 918  $00:58:56.130 \longrightarrow 00:58:58.350$  are not that familiar with it?
- 919 00:58:58.350 --> 00:59:01.667 <v -> The HEARTS Initiative is a platform initiative</v>
- 920 00:59:01.667 --> 00:59:02.867 for the Americas.
- 921  $00:59:02.867 \longrightarrow 00:59:04.350$  There are 12 countries
- 922 00:59:04.350 --> 00:59:07.710 that adopted the HEARTS Initiative
- 923 00:59:07.710 --> 00:59:11.760 directed to better control hypertension,
- $924~00{:}59{:}11.760 \dashrightarrow 00{:}59{:}16.410$  and HEARTS is based on a team-based approach protocol
- 925 00:59:16.410 --> 00:59:20.580 for clinical practice guidelines in the country,
- 926 00:59:20.580 --> 00:59:22.440 measuring cardiovascular risk
- 927 00:59:22.440 --> 00:59:27.300 as part of the management of patients with hypertension
- 928 00:59:27.300 --> 00:59:30.810 and providing free access to medication,
- 929 00:59:30.810 --> 00:59:34.590 in particular, fixed-dose combinations,
- 930 00:59:34.590 --> 00:59:37.500 which are supposed to improve adherence,
- 931 00:59:37.500 --> 00:59:41.430 because these people had and have comorbidities
- $932\ 00:59:41.430 \longrightarrow 00:59:44.400$  and sometimes have to take many medications,
- $933\ 00:59:44.400 \longrightarrow 00:59:49.400$  so these fixed-dose combinations are an alternative.
- 934 00:59:49.678 --> 00:59:53.541 Those are the components of the HEARTS Initiative
- 935 00:59:53.541 --> 00:59:56.949 in the Americas, and we have 12 countries at the moment
- 936  $00:59:56.949 \longrightarrow 00:59:59.160$  as part the initiative.
- 937 00:59:59.160 --> 01:00:02.289 <v Donna>And who's paying for all these medications?</v>
- 938 01:00:02.289 --> 01:00:03.400 <v ->Each government.</v>

- 939 01:00:03.400 --> 01:00:04.380 I mean, each government.
- 940 01:00:04.380 --> 01:00:06.360 They don't receive...
- 941 01:00:06.360 --> 01:00:10.053 Countries don't receive any financial support.
- 942 01:00:10.968 --> 01:00:14.468 Technical support, yes, but not financial.
- 943 01:00:17.050 --> 01:00:19.380 <v Donna>Okay, well, it is 13:00,</v>
- $944\ 01:00:19.380 \longrightarrow 01:00:22.680$  so this was an incredibly interesting talk.
- 945 01:00:22.680  $\rightarrow$  01:00:25.170 I would've loved to have asked more about equity,
- $946\ 01:00:25.170 \longrightarrow 01:00:27.090$  which is a very hot topic around here
- 947 01:00:27.090 --> 01:00:29.910 at the Yale School of Public Health and elsewhere,
- $948\ 01:00:29.910 \longrightarrow 01:00:32.790$  but maybe we can save that for another time.
- 949 01:00:32.790 --> 01:00:34.200 And thank you so much, Vilma,
- $950\ 01:00:34.200$  --> 01:00:39.200 for coming and providing such a mazing information.
- 951 01:00:40.358 --> 01:00:41.874 <v ->Thank you very much.</v>
- $952\ 01:00:41.874$  --> 01:00:44.870 Thank you very much for giving me the opportunity.
- 953 01:00:44.870 --> 01:00:46.786 <v ->Yeah.</v> <v ->You are like a star.</v>
- 954 01:00:46.786 --> 01:00:48.545 (attendees laughing) <v -> Thank you.</v>
- 955 01:00:48.545 --> 01:00:51.795 (attendees chattering)
- 957 01:00:55.050 --> 01:00:56.333 <v Attendee 2>Hi, how are you?</v>