Impact of increased praziquantel frequency on childhood fibrosis in persistent schistosomiasis morbidity hotspots: FibroScHot. A Phase IV Individual Randomised Superiority Trial.

Basic Results

Clinical Trial Registration: ISRCTN 16994599

1. Participant Flow

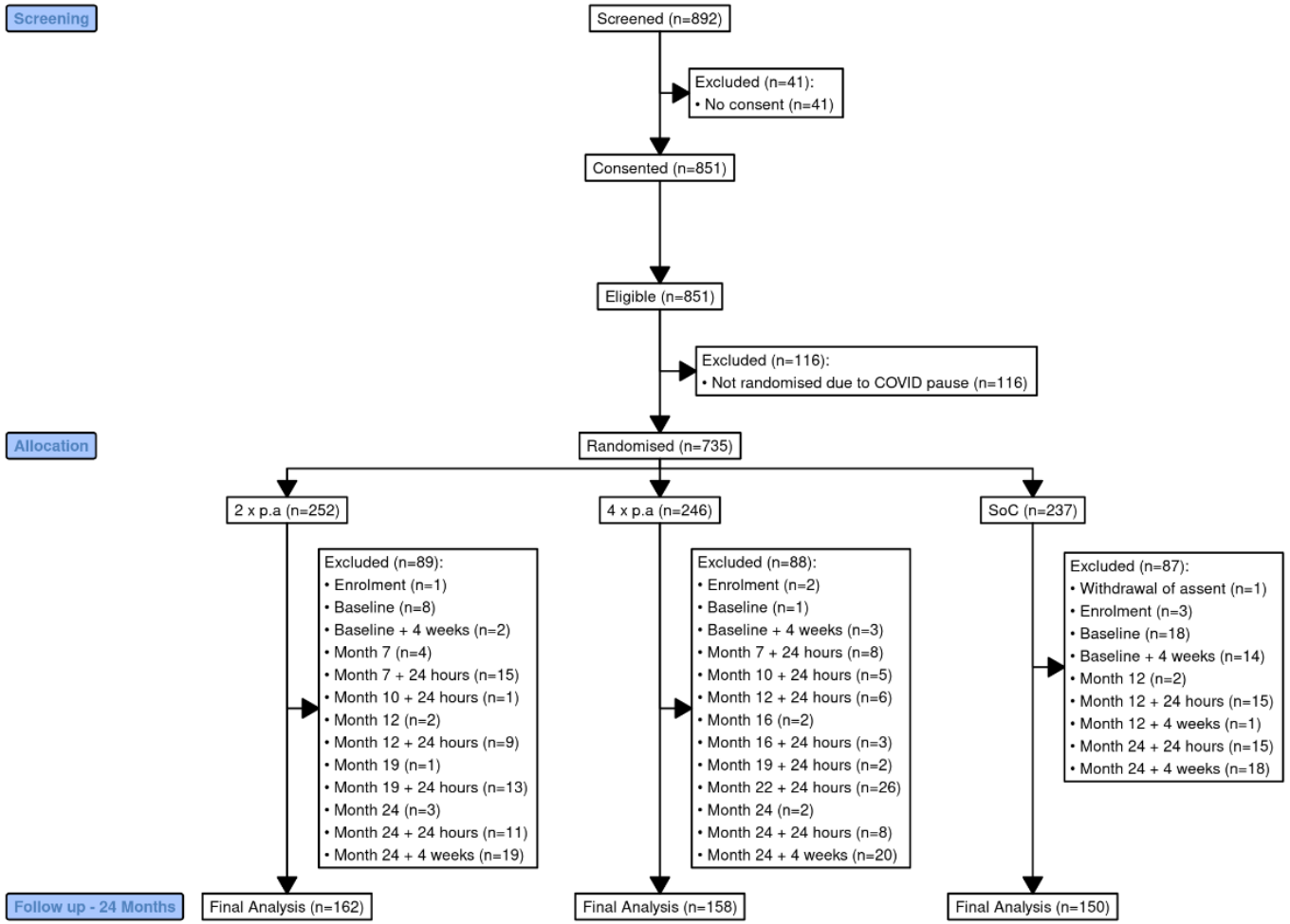

Figure 1.1 Consort diagram for the primary outcome – prevalence of periportal fibrosis. Participants noted as being excluded from the analysis at 24 months +24 hours or 24 months +4 weeks did not have ultrasound data at 24 months but they were seen after 24 months

2. Baseline Characteristics

Table 2.1. Summary demographic statistics of the eligible population

Variable	SoC	2 x p.a	4 x p.a	Total
Observation	237	252	246	735
Sex				
Female	110/237 (46%)	108/252 (43%)	116/246 (47%)	334/735 (45%)
Male	127/237 (54%)	144/252 (57%)	130/246 (53%)	401/735 (55%)
Age				
Valid Obs.	237	252	246	735
Mean (SD)	9.76 (2.26)	9.95 (2.12)	9.97 (2.22)	9.90 (2.20)
Median [Min, Max]	10.0 [6.00, 14.0]	10.0 [6.00, 14.0]	10.0 [6.00, 14.0]	10.0 [6.00, 14.0]
School				
Buhirigi	134/237 (57%)	150/252 (60%)	144/246 (59%)	428/735 (58%)
Kaiso	103/237 (43%)	102/252 (40%)	102/246 (41%)	307/735 (42%)
Length of residency in District				
>2-4 Years	40/237 (17%)	43/252 (17%)	37/246 (15%)	120/735 (16%)
>4 years	197/237 (83%)	209/252 (83%)	209/246 (85%)	615/735 (84%)

Table 2.2. Summary statistics of periportal fibrosis at baseline

Fibrosis at baseline				
	SoC	**2 x p.a**	**4 x p.a**	**Total**
Yes	4/193 (2%)	6/216 (3%)	10/223 (4%)	20/632 (3%)
No	189/193 (98%)	210/216 (97%)	213/223 (96%)	612/632 (97%)
Missing	44 (19%)	36 (14%)	23 (9%)	103 (14%)

Table 2.3. Summary statistics of infection intensity at baseline

Baseline epg				
	SoC	**2 x p.a**	**4 x p.a**	**Total**
Valid Obs.	227	239	234	700
Mean (SD)	175 (353)	205 (397)	226 (473)	202 (411)
Median [Min, Max]	24.0 [0, 2320]	36.0 [0, 2930]	48.0 [0, 3590]	36.0 [0, 3590]
Missing	10 (4%)	13 (5%)	12 (5%)	35 (5%)

3. Outcome Measures

3.1 Primary outcome

Table 3.1. Summary results for periportal fibrosis at 24-months

Variable	SoC	2 x p.a	4 x p.a	Total
Observation	237	252	246	735
Fibrosis at 24 months				
Yes	4/150 (3%)	9/162 (6%)	5/158 (3%)	18/470 (4%)
No	146/150 (97%)	153/162 (94%)	153/158 (97%)	452/470 (96%)
Missing	87 (37%)	90 (36%)	88 (36%)	265 (36%)
Adjusted* log odds (95% CI) at 24-months	Reference	0.788 (-0.431, 2.01)	0.101 (-1.25, 1.45)	-

*Adjusted for baseline periportal fibrosis, baseline log(egg count+1), residency and school

3.2 Secondary outcome

Table 3.2. Summary results for *Schistosoma mansoni* infection intensity at 24-months

Variable	SoC	2 x p.a	4 x p.a	Total
Observation	237	252	246	735
24 Month epg				
Valid Obs.	153	169	165	487
Mean (SD)	88.4 (233)	86.2 (272)	27.5 (71.5)	67.0 (212)
Median [Min, Max]	0 [0, 1380]	0 [0, 1710]	0 [0, 420]	0 [0, 1710]
Missing	84 (35%)	83 (33%)	81 (33%)	248 (34%)
Adjusted* difference (95% CI) at 24-months	Reference	0.882 (0.580, 1.342)	0.527 (0.346, 0.802)	-
Adjusted* difference (95% CI) at 24-months	1.13 (0.745, 1.72)	Reference	0.597 (0.395, 0.901)	-

*Adjusted for baseline log(egg count+1) and school.

4. Adverse Events

Table 4.1 Summary of adverse events recorded across all treatment visits

Adverse event	SoC	2 x p.a.	4 x p.a.	TOTAL
Abdominal pains without nausea	46	54	76	176
Abdominal pains with nausea	24	16	35	75
Diarrhoea	3	3	8	14
Nausea	3	2	5	10
Vomiting	5	4	8	17
Pruritus	5	0	7	12
Rash	0	2	2	4
Urticaria	2	1	3	6
Facial Oedema	0	0	1	1
Headache	3	10	25	38
Vertigo	1	1	4	6
Other	0	1	1	2
TOTAL	92	94	175	361