Self start HOME HIV Post exposure prophylaxis (PEPSE), to reduce time to first dose and increase efficacy: A RCT

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Background

Effectiveness of Post exposure prophylaxis (PEPSE) correlates with speed of uptake following HIV exposure.[1] Time taken travelling to and obtaining PEPSE at sexual health/ emergency units can reduce efficacy and prevent people accessing PEPSE.

We hypothesised that advanced provision of a 5-day PEP starter pack (HOME PEPSE) for men who have sex with men (MSM) to keep at home and self- initiate if required, would reduce time to first dose following HIV exposure, but not impact HIV risk behaviour.

Materials and Methods

Phase IV, randomised, prospective, open label, study. MSM at medium risk of acquiring HIV were randomized (1:1) to immediate (ARM A) or deferred (ARM B) Home PEPSE. Duration of study was 48 weeks (Arm A) and 72 weeks for (Arm B) who accessed PEPSE through standard of care from week 0-48 and received HOME PEPSE week 48-72.

Every 12 weeks, participants self- completed mental health/ risk behaviour surveys and had HIV/STI testing. HOME PEPSE comprised a 5-day pack of FTC-TDF/Maraviroc taken following potential exposure to HIV. Upon uptake, participants completed a risk questionnaire; PEPSE continuation was physician directed. Appropriate uses of PEP were included in primary analysis. Time to first dose between treatment arms was compared using a two-sided Mann-Whitney U test. Missed opportunity to uptake PEPSE was defined as sex in which PEPSE was indicated according to UK PEPSE guidelines. [2]

Results

Participant characteristics

139 participants were randomised: 69 (ARM A) and 70 (ARM B). Median age 30 years [IQR: 26-39], 75% white, 55% UK born and 72% university educated (Table 1). 33 in ARM A and 15 in ARM B were eligible for primary analysis.

There was one HIV seroconversion in 231 years of person- years follow up . This individual had repeatedly been advised to start PrEP due to his ongoing high risk sexual behaviour. There were 58 cases bacterial STI during the study , 27 in group A and 31 in group B (p= 0.707).

Uptake of PEPSE

The most reported reason for PEPSE uptake was receptive anal sex with a man of unknown HIV status (81% cases).

Uptake of HOME PEPSE was appropriate in 29/ 33 cases (88%, 95% CI: 73-95%)

Median time from exposure to first dose was 7.6 hours [3.0,20.9] for ARM A and 28.5 hours [17.3,34.0] for ARM B (p < 0.01). One participant in each arm took PEPSE >50 hrs before having their first dose (Figure 1). 6 people in arm A and 2 in arm B accessed PEPSE more than once in 48 weeks.

22/26 people who initiated HOME PEPSE kept it at home, 1/26 kept in a bag, 3/26 other. 2/66 (3%) reported giving their HOME PEPSE to other people to use.

Figure 1: Median time from exposure to first dose for each participant who accessed PEPSE baseline to week 48

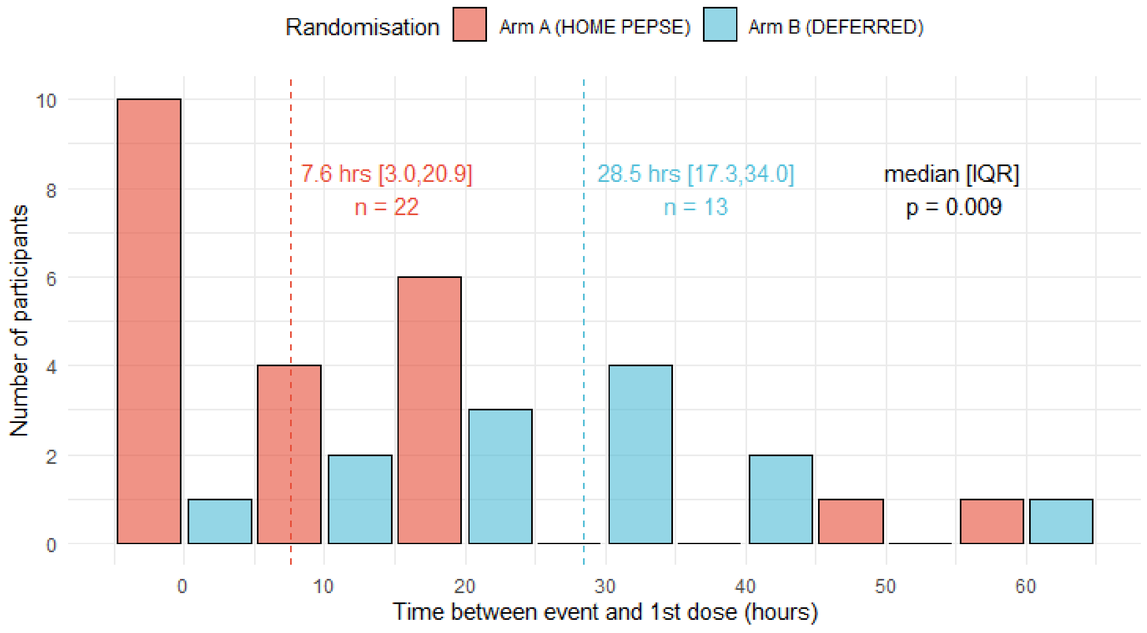


Table 2: Number of times an individual took PEPSE from 0 to week 48

No. of times accessed PEP	ARM A (HOME PEPSE)	ARM B (Deferred)
1	16	12
2	5	2
3	1	0

Risk Behaviour

No change in number of condomless anal sex acts in previous 3 months from week 0 to 48 in both arms (512 versus 911: p = 0.215). Number of bacterial STI increased decreased over time in both arms (p=0.707).

Table 3: Number of bacterial STIs diagnosed per visit from 0 to week 48

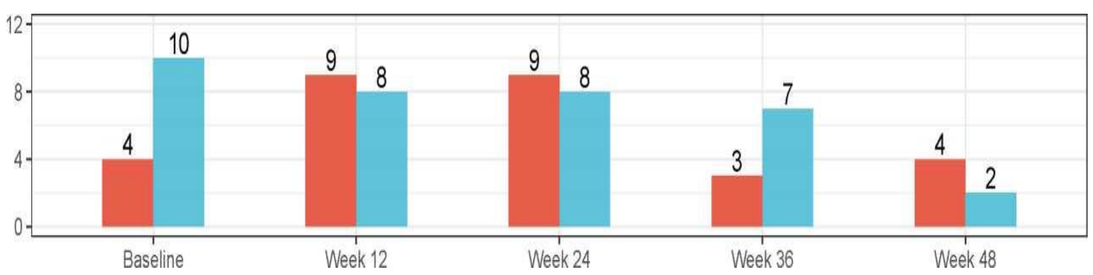


Table 1. Baseline demographic characteristics.

	Entire Sample n = 135	ARM A (HOME PEPSE) n = 66	ARM B (DEFERRED) n = 69
Age at registration	30 [26, 39]	30 [27,40]	29 [26,37]
Ethnicity			
White/Caucasian	101 (75%)	52 (79%)	49 (71%)
Black or African	9 (7%)	4 (6%)	5 (7%)
Oriental	6 (4%)	2 (3%)	4 (6%)
Other	19 (14%)	8 (12%)	11 (16%)
University degree	97 (72%)	45 (68%)	52 (75%)
Employment status			
Full time	98 (73%)	46 (70%)	52 (75%)
Part time	9 (7%)	4 (6%)	5 (7%)
Education	20 (15%)	11 (17%)	9 (13%)
Unemployed	8 (6%)	5 (8%)	3 (4%)
Born in the UK	74 (55%)	31 (47%)	43 (62%)
Not currently in a relationship	88 (65%)	43 (75%)	45 (75%)
Circumcised	37 (27%)	19 (29%)	18 (26%)
STI diagnosed in past 12 months			
Any	75 (56%)	34 (52%)	41 (59%)
Bacterial [a]	71 (53%)	32 (49%)	39 (57%)
Rectal [b]	42 (31%)	17 (26%)	25 (36%)
Number of HIV tests in past 12 months	3 [2,4]	3 [2,4]	3 [2,4]
Used PEPSE in past 12 months	53 (39%)	30 (46%)	23 (33%)

Missed opportunities for PEPSE uptake

ARM B had almost double the number (same median and IQR) of missed opportunities for PEPSE uptake than ARM A (268 versus 474 :p=0.625): this result was skewed as 9/12 (75%) participants reporting >10 missed opportunities for PEPSE were in ARM B. There was a significant (p = 0.0014) difference between the number of missed opportunities in each arm at week 36 only.

Figure 2: Bar plot of the number of missed opportunities for PEPSE by treatment arm and timepoint

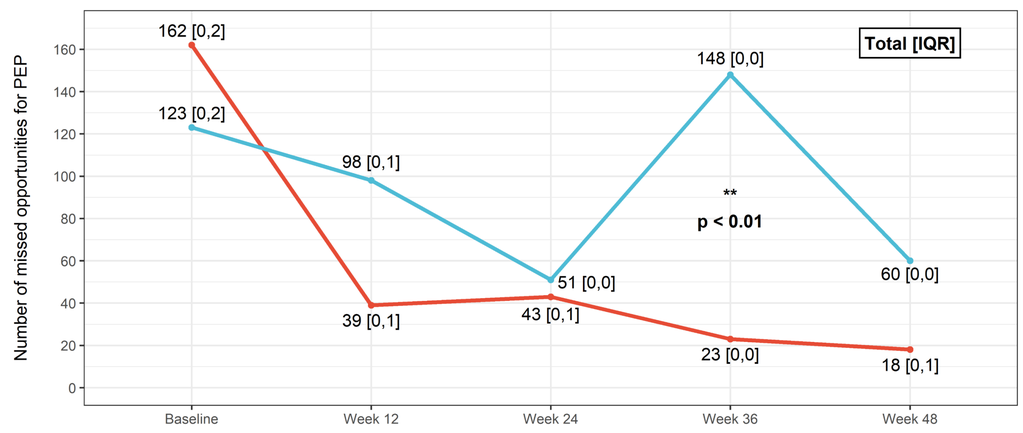
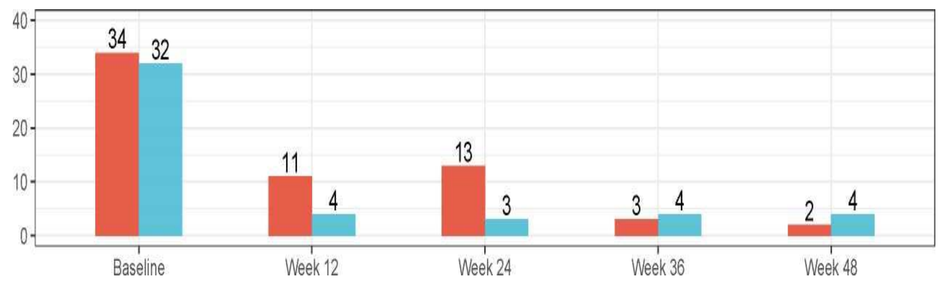


Table 3: PEPSE uptake from 0 to week 48 (baseline is PEPSE in past 12 months)



Safety

HOME PEPSE was well tolerated. There were no serious adverse events (SAEs). Solicited AEs from the first five days after starting HOME PEPSE showed that headache and fatigue were the most reported systemic reactions.

Interpretation

- HOME PEPSE was taken appropriately by MSM
- HOME PEPSE reduced time from exposure to first dose by 20 hours, with no impact on safety
- For MSM not wanting to take PrEP, or those with sexual practices in which they cannot predict sex, HOME PEPSE may be a valuable HIV prevention tool
- Clinical guidelines should consider this as a prevention option

References:

1. Tsai C, et al. J Virol 1998; 72:4265–73
2. Cresswell F et al. 2015. Int J STD AIDS. 2016 Aug;27(9):713-38.

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