PRELIMINARY ANALYSIS OF THE SUPERDOT-C STUDY: A CLUSTER RANDOMISED CONTROLLED TRIAL OF PHARMACY LED VERSUS CONVENTIONAL TREATMENT FOR HCV POSITIVE PATIENTS RECEIVING DAILY OPIOD SUBSTITUTION THERAPY WITHIN NHS SCOTLAND

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SuperDOT-C

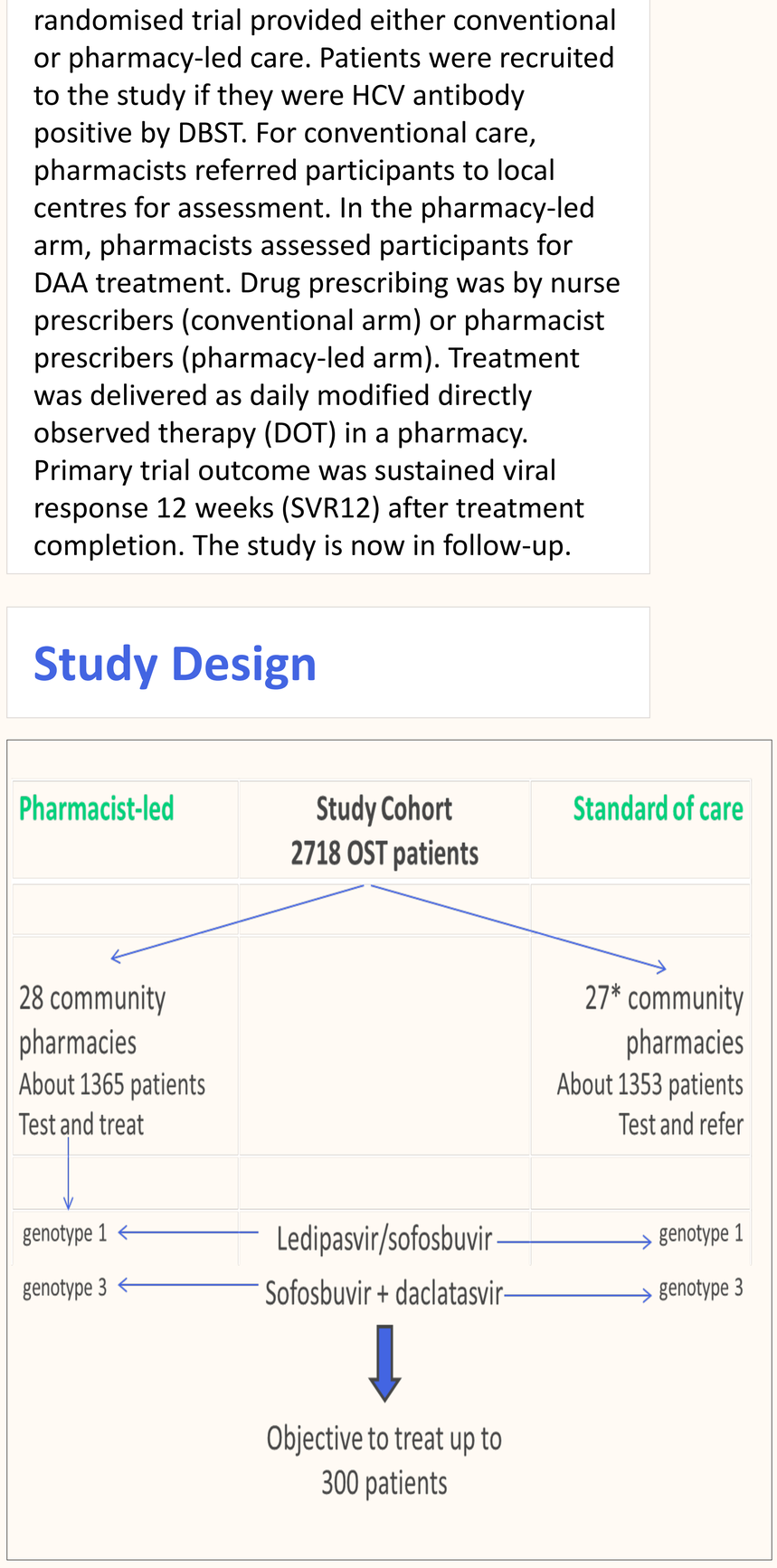
Aim

Elimination of Hepatitis C (HCV) requires greater access to testing and treatment to at-risk groups. People prescribed Opioid Substitution Therapy (OST) are at high risk of HCV infection. Community pharmacists see this group frequently to provide OST [1]. This study evaluates the effect of community pharmacists managing the treatment of patients, comparing the number of patients cured, versus the number cured with the conventional treatment pathway.

Methods

55 community pharmacies in a cluster randomised trial provided either conventional or pharmacy-led care. Patients were recruited to the study if they were HCV antibody positive by DBST. For conventional care, pharmacists referred participants to local centres for assessment. In the pharmacy-led arm, pharmacists assessed participants for DAA treatment. Drug prescribing was by nurse prescribers (conventional arm) or pharmacist prescribers (pharmacy-led arm). Treatment was delivered as daily modified directly observed therapy (DOT) in a pharmacy. Primary trial outcome was sustained viral response 12 weeks (SVR12) after treatment completion. The study is now in follow-up.

Study Design

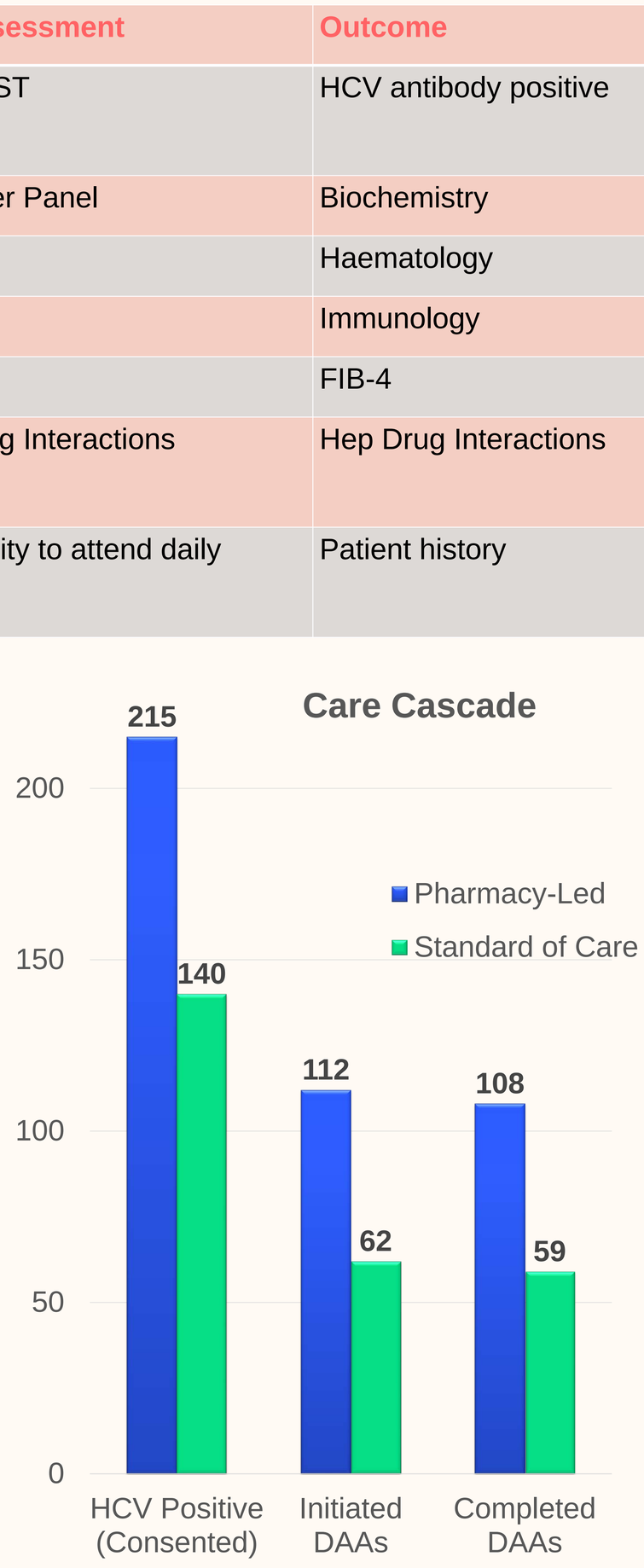


Participant Recruitment

	Pharmacy-Led (ITT%)	Standard of care (ITT%)
Available participants	1365	1353
Estimated number with HCV infection	545 (100)	540 (100)
Accepted offer of a test	250 (46)	139 (26)
DBST Ab negative	176	106
New DBST Ab positive	74	33

Patient Assessment

Assessment	Outcome
DBST	HCV antibody positive
Liver Panel	Biochemistry
	Haematology
	Immunology
	FIB-4
Drug Interactions	Hep Drug Interactions
Ability to attend daily	Patient history



Interim Results

355 participants were recruited from a pool of 2718 OST recipients, 215 in the pharmacy-led arm (1365 OST recipients) and 140 in the conventional arm (1353 OST recipients). In the pharmacy-led arm; 112 (52%) accessed treatment, 83 have achieved SVR12 so far with 3 failures. 6 participants dropped out (2 deaths, 2 patient choice, 1 pregnancy and 1 moved away). Of the conventional arm patients; 62 (44%) received treatment, 36 have achieved SVR12 so far, 2 failed. 3 dropped out (1 patient choice, 2 moved away).

Conclusions

Preliminary analysis suggests that the pharmacy-led pathway increased both consent to, and initiation of, treatment. The offer of testing, assessment and treatment with DAAs in a pharmacy increased HCV treatment uptake in people on OST. The delivery of treatment within the familiar setting of the community pharmacy was central to the success of the model.

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Reference

Radley A, Tait J, Dillon JF. DOT-C: A Cluster Randomised Feasibility Trial Evaluating Directly Observed Anti-HCV Therapy in a population receiving opioid substitute therapy from community pharmacy. International Journal of Drug Policy 2017 DOI: 10.1016/j.drugpo.2017.05.042

Acknowledgements

The study thanks all pharmacy staff, nurses and participants who took part in SuperDOT-C.

SuperDOT-C was funded by the Scottish Government with free drug provided by Bristol Myers-Squibb and Gilead Sciences Inc.