

## Abstract

The effectiveness of modified-directly observed therapy (m-DOT), an adherence support intervention adapted from TB DOTS programmes, has been documented. Describing the implementation process and acceptability of this intervention is important for scaling up, replication in other settings and future research. In a randomised trial in Mombasa, Kenya, patients were assigned to m-DOT or standard of care for 24 weeks. m-DOT entailed twice weekly visits to a health centre for medication collection, ongoing adherence counselling and nurse-observed pill ingestion. Community health workers (CHWs) traced non-attendees, observing pill taking at participant's home. Using process indicators and a semi-structured questionnaire, implementation of m-DOT was evaluated among 94 participants who completed 24 weeks m-DOT (81%; 94/116). Two-thirds of m-DOT recipients were female (64%; 74/116) and a mean 37 years ( $SD = 7.8$ ). Selection of the m-DOT observation site was determined by proximity to home for 73% (69/94), with the remainder choosing sites near their workplace, or due to perceived high-quality services. A median 42 of 48 scheduled m-DOT visits (IQR = 28-45) were attended. Most found m-DOT is very useful (87%; 82/94) and had positive attitudes to the services. A high proportion received CHWs home visits (96%; 90/94) and looked forward to these. Use of CHWs and several satellite observation sites facilitated provision of services closer to patient's homes. A substantial number, however, thought 24 weeks of m-DOT was too long (43%; 42/94). Our experience suggests that m-DOT services could be implemented widely and are acceptable if delivered with adequate attention to coordination, provision of a broad set of interventions, shifting tasks to less-specialised workers and integration within the health system. m-DOT programmes should utilise existing resources while simultaneously expanding capacity within communities and the public sector. These findings could be used to inform replication of such services and to improve the design of m-DOT in future studies.