

# Feasibility and Acceptability of the Modified Antiretroviral Treatment Access Study (MARTAS) Intervention Based on a Pilot Study in Ukraine

Journal of the International  
Association of Providers of AIDS Care  
Volume 18: 1-6  
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DOI: 10.1177/2325958218823257  
journals.sagepub.com/home/jia



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## Abstract

We conducted a pilot of the Modified Antiretroviral Treatment Access Study (MARTAS), a linkage to HIV treatment intervention, prior to implementing a multisite randomized controlled trial (RCT) in Ukraine. The objectives of the pilot were to assess the feasibility and acceptability of the MARTAS intervention among a small sample of adults recently diagnosed with HIV at specialty clinics in the Mykolaiv region of Ukraine in 2015. The adapted intervention consisted of up to 6 individual-level sessions with a linkage coordinator (nurse) over a 90-day period. Overall, 22 persons participated in the pilot. On average, participants received 4.2 sessions and 14 participants linked to HIV care within 3 months of study enrollment. All 18 participants who completed the acceptability survey expressed high satisfaction with their interaction with their linkage coordinator. The results of the pilot demonstrated feasibility and acceptability of the MARTAS intervention in advance of a larger scale RCT in Ukraine.

## Keywords

HIV, case management, linkage to HIV care, feasibility, acceptability

Date received: 9 January 2018; revised: 22 November 2018; accepted: 10 December 2018.

## Introduction

Ukraine, with an estimated HIV prevalence of 0.9% among adults aged 15 to 49 years (2015), faces one of the largest HIV epidemics in Eastern Europe and Central Asia.<sup>1</sup> At the end of 2014, an estimated 223 000 people were living with HIV (PLHIV) in Ukraine<sup>2</sup>; only 138 000 (62%) were engaged in HIV care.<sup>2</sup> Of these, 58% had CD4 count below  $350 \times 10^6$  cells/L, suggesting delayed linkage to HIV treatment.<sup>3</sup> As of 2015, more than 23 000 people were tested HIV positive in Ukraine,<sup>3</sup> and 16 000 (70%) were linked to HIV care during the year, including individuals diagnosed either in 2015 or previously. Lack of a case-based surveillance system in Ukraine makes it difficult to measure annual linkage-to-care rates among those diagnosed with HIV.<sup>3</sup> In 2015, retention in HIV care (determined as at least one clinical visit during 12 months) was 77.7% with only 70% of this proportion receiving antiretroviral therapy (ART).<sup>3</sup> Delays in both linkage to care and ART initiation result in poor treatment outcomes and further spread of the HIV epidemic.<sup>4-6</sup>

The most recent estimates (2017) indicate 10 900 PLHIV in the Mykolaiv region, with 8846 (81%) registered at the AIDS

Center, 7201 (66%) retained in HIV care, and 5692 (52%) receiving ART. As of 2017, 990 Mykolaiv residents tested HIV positive and 923 linked to HIV care, although this number includes individuals who tested HIV positive prior to 2017.<sup>7</sup> Again, lack of a case-based surveillance prevents calculation of linkage to HIV care estimates. Available data suggest an urgent need to improve linkage to HIV services.<sup>8,9</sup>

The Antiretroviral Treatment Access Study (ARTAS) is an individual-level, multisession, time-limited case management intervention with demonstrated effectiveness in linking persons

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### What Do We Already Know about This Topic?

Several interventions and promising practices for improving linkage and maintaining patient engagement in HIV care were found effective, including strengths-based case management Antiretroviral Treatment Access Study (ARTAS) intervention in the United States

### How Does Your Research Contribute to the Field?

This research describes the results of the study to assess feasibility and acceptability of the individual-level, multi-session, time-limited case management intervention—Modified ARTAS (MARTAS) in Ukraine.

### What Are Your Research's Implications toward Theory, Practice, or Policy?

The results show feasibility and acceptability of the MARTAS intervention in the Ukrainian health care and provide the rationale for a large-scale randomized controlled trial to assess the effectiveness of the MARTAS intervention to link HIV-positive adults to HIV care in Ukraine.

recently diagnosed with HIV to medical care in the United States.<sup>10–12</sup> Antiretroviral Treatment Access Study uses the strengths-based case management model,<sup>13,14</sup> which empowers participants to apply their internal strengths to achieve life goals, and is grounded in behavioral theories of empowerment and self-efficacy.<sup>15,16</sup>

Linkage to HIV care, our pilot study and randomized controlled trial (RCT) primary outcome, is defined as an initial visit followed by official registration at the AIDS Center. The process of registration at the AIDS Center requires a person diagnosed with HIV to undergo several clinical and laboratory examinations.<sup>17</sup> Because of this and other factors specific to the Ukrainian context, the successful transfer of the ARTAS intervention to a new setting required its adaptation.<sup>18</sup> The modifications to the original ARTAS intervention were made based on formative research results<sup>19</sup> and included intervention delivery at specialty clinics, called specialized healthcare facilities (SHCFs) in Ukraine, which provide treatment for infectious diseases, sexually transmitted infections, and substance abuse. The modified ARTAS (MARTAS) intervention also included addressing stigma, fear of HIV status disclosure, depression, and addiction, based on participant needs, through referrals to psychological, addiction, and other services. Finally, other modifications included delivery of the intervention by clinic nurses who performed up to 6 sessions (including up to 3 telephone sessions).

This article describes the results of the pilot study to assess feasibility and acceptability of MARTAS in a high HIV burden region of Ukraine prior to the implementation of the intervention in the multisite RCT.<sup>2</sup>

## Methods

All pilot participants were recruited in the Mykolaiv region between January and April 2015, at 3 urban specialty clinics: Dermato-Venereological Dispensary, Narcology Dispensary, and Infectious Diseases Hospital. These clinics typically serve key populations such as people who inject drugs.

The physicians in each facility informed potential participants about the study objectives and procedures after HIV posttest counseling or during their regular clinical visit. Potentially eligible patients of these specialty clinics were referred by their physicians to the research associates (RAs). Eligibility criteria included being 18 years or older, recently diagnosed (tested HIV positive within the past 6 months), fluent in Russian or Ukrainian, and able to read/understand and sign an informed consent form. The exclusion criteria were cognitive impairment, pending legal issues, and being already registered at the AIDS Center. Physicians in each type of clinic were given specific instructions on how to refer potentially eligible patients to the RA. After a patient received information about the study, the RA approached the patient to confirm eligibility and they proceeded to a private area where the RA briefly explained the study aims and procedures. All eligible patients who agreed to participate were asked to sign the informed consent form that provided detailed information on all study procedures, including collection and use of medical and self-reported information. After providing written informed consent, participants completed an RA-administered, structured baseline questionnaire.

Upon completion of the baseline questionnaire, the RA introduced each participant to the linkage coordinator (LC) to arrange a time for the first in-person intervention session. Additional MARTAS sessions could be conducted in person or through the phone. The LCs were allowed to call clients only from the separate session room, keeping the clients' phone numbers in a locked cabinet. Linkage coordinators were nurses who completed a 3-day training on the MARTAS intervention and the National Institutes of Health online training "Protecting Human Research Participants." After completion of the intervention, clients were scheduled for the RA-administered 3-month follow-up questionnaire and the intervention acceptability survey.

Feasibility of the intervention was defined a priori as achieving outcomes similar to those of the ARTAS effectiveness trial. For example, we assessed the proportion of the pilot participants who received at least one session with LC (participation in the intervention), average number of sessions received by a participant, and proportion of those linked to HIV care within 3 months (ie, initial visit followed by official registration at the AIDS Center). We used client medical records at the AIDS Center as the primary source of information about participant linkage to HIV care to address limitations of self-report.<sup>11,20</sup> The Mykolaiv (AIDS Center, personal communication) designated professional with official permission to access medical records performed the review of patient medical charts. Data from the medical chart

**Table 1.** MARTAS Intervention Indicators at Urban SHCFs in Mykolaiv Region of Ukraine, 2015.

Indicator	N/Mean/%		
Data from LC reports			
Monthly indicator of participant recruitment: 3 new participants per site per month enrolled in the study	1.9 per site per month		
Proportion of the participants who received at least 1 session, of the study participants who provided informed consent	20/22/91%		
Proportion of the participants whose strengths assessment was conducted at the sessions, of all participants who started participating in the intervention	20/20/100%		
Number of sessions received by participants who completed participation in the intervention (all sessions, face-to-face sessions, telephone sessions: average per participant)	Total: 84; 4.2 per participant Face-to-face sessions: 65; 3.3 per participant Telephone sessions: 19; 0.95 per participant		
Average face-to-face session time (minutes)	62.4 minutes		
Average telephone session time (minutes)	22.5 minutes (based on the data of 11 participants)		
Number of referrals made—total and average per participant for all participants who completed participation in the intervention (total, average per participant)	46 referrals; 2.3 per participant		
Proportion of the participants who started intervention and were referred to the AIDS Center	16/20/80%		
Visited the AIDS center among those who started participating in the intervention	16/20/80%		
Of those who visited the AIDS Center:	Total: 16 visited		
After Session 1	0		
After Session 2	6		
After Session 3	1		
After Session 4	3		
After Session 5	6		
Data from medical records			
Visited the AIDS Center within 3 months after enrollment in the study	16/22/72.7% (of the total number of participants)		
Linked to HIV care (completed registration procedure at the AIDS Center)	15/22/68.2% (of the total number of participants)		
Linked to HIV care within 3 months after enrollment in the study	15/20/75.0% (of those received at least one MARTAS session)		
	14/22/63.6% (of the total number of participants)		
Number of visits to the AIDS Center for those who linked to HIV care within 3 months after entering the study	14/20/70.0% (of those received at least one MARTAS session)		
	Visits per participant	# of participants	Total # of visits
	1	3	3
	2	3	6
	3	1	3
	4	2	8
	5	4	20
	6	1	6
		14	46

Abbreviations: LC, linkage coordinator; MARTAS, modified ARTAS; SHCFs, specialized healthcare facilities.

review were provided by this AIDS Center professional to the study RAs biweekly.

Acceptability of the MARTAS intervention was measured using a structured questionnaire that assessed participants' experience (experience and satisfaction with the intervention), effective attitude (attitude toward the intervention), and perceived effectiveness (the extent to which the intervention is perceived as likely to achieve its purpose).

The study protocol, data collection tools, and data security procedures were approved by the institutional review board at the Ukrainian Institute on Public Health Policy and the Science Integrity Branch of the Centers for Disease Control and Prevention (CDC) in Atlanta.

## Results

During the pilot, 24 patients at 3 specialty clinics in the Mykolaiv region were screened for eligibility and 23 consented to participate in the study. One participant was later excluded from the study based on the exclusion criteria. Therefore, 22 persons participated in the pilot study. Their mean age was 39.8 years; 13 (59.1%) were male; and most participants (13; 59.1%) were in stable relationships. Nineteen (86.4%) participants had a high school education or less; 19 (86.4%) were employed during the past year. Current monthly income of approximately half of the participants was less than 2000 Ukrainian Hryvnia (equivalent to 77 USD). Nine (40.9%)

participants reported occasionally not having money for their basic needs during past year, although all participants reported having a stable place to live. Twenty of the 22 pilot participants received at least one MARTAS session (Table 1).

Intervention participants received 4.2 intervention sessions on average (3.3 face-to-face sessions per participant; 0.95 telephone sessions per participant). Average duration was 62.4 minutes for face-to-face sessions and 22.5 minutes for telephone sessions. Strengths assessment (the MARTAS core element) was conducted for each pilot participant during the sessions. Each participant, focusing on his or her self-identified strengths, created an action plan with specific goals, including linking to HIV medical care. Each participant received on average 2.3 referrals to the AIDS Center, addiction treatment, psychological services, and nongovernmental organizations.

Review of the participants' medical charts at the AIDS Center showed that 14 participants completed the registration procedure at the AIDS Center within 3-month period, having made on average 3.3 clinical visits to the AIDS Center.

Overall, 18 participants who received at least one MARTAS session completed the acceptability survey (Table 2). All 18 were satisfied with the LC-delivered intervention sessions, and 16 considered their LC as knowledgeable about HIV. Fifteen participants positively assessed the intervention and the role of the LC in their linkage to HIV medical care. Finally, all respondents thought that LCs would be useful in helping others link to HIV care in the future.

## Discussion

The study results demonstrated both feasibility and acceptability of the MARTAS intervention to improve linkage to HIV care for adults recently diagnosed with HIV in SHCFs.

The first case management session was mostly delivered on the day of the participant baseline interview and after his or her in-person meeting with the LC. This modification of ARTAS, along with the delivery of the intervention by a regular clinical staff member (a nurse), ensured the intervention feasibility, reflected by a high uptake of the intervention (20 of 22, or 90.9% of the pilot participants attended MARTAS sessions). The average number of intervention sessions per participant (both face-to-face and telephone; mean 4.2, median 4.5) was higher compared to the number of face-to-face sessions participants received in the US-based ARTAS-II study (mean 2.3 and median 2 sessions).<sup>11</sup>

In our pilot study, the proportion of those linked to HIV care (70% among those who received MARTAS and 63.6% among all study participants) was lower compared to the ARTAS results (78% of the intervention participants).<sup>10</sup> This difference may be attributed to a complex, time-consuming process of registration at the AIDS Center in Ukraine.<sup>21</sup> Lower linkage to HIV care may also be a result of inconsistent outcome definitions across the 2 studies: in the MARTAS pilot study, the main outcome was defined as "completed registration at the AIDS Center within a 3-month period,"

**Table 2.** MARTAS Intervention Acceptability Indicators at Urban SHCFs in Mykolaiv Region of Ukraine, 2015.

Question	Grade	N/Mean
Completed MARTAS satisfaction questionnaire		19
In the past 3 months, have you met with an LC?	Yes (filter for all following questions)	18
	No	1
How many times have you met with an LC in the past 3 months? <sup>a</sup>	Mean (SD)	3.35 (1.41)
	Median (IQR)	3.00 (2.0)
How much did you enjoy meeting(s) with the LC?	Very much	12
	Somewhat	6
	Not very much	
	Not at all	
How much did your appointment(s) with the LC meet your HIV concerns?	Very much	8
	Somewhat	10
	Not very much	
	Not at all	
How much did your appointment(s) with the LC meet your other health concerns?	Very much	10
	Somewhat	5
	Not very much	1
	Not at all	1
Was the LC knowledgeable about HIV issues?	Yes	9
	No	9
	Definitely yes	
	Definitely no	
Was the LC knowledgeable about other health issues?	Yes	4
	No	12
	Definitely yes	
	Definitely no	
Did the LC help you connect to HIV health care?	Yes	6
	No	9
	Definitely yes	
	Definitely no	
Did the LC help you connect to other healthcare services (psychological, psychiatry, STI, addiction, etc)?	Yes	12
	No	4
	Definitely yes	
	Definitely no	
Do you think an LC would be useful in helping others connect to HIV care?	Yes	2
	No	5
	Definitely yes	13
	Definitely no	
Do you think an LC would be useful in helping others connect to other health care services?	Yes	3
	No	15
	Definitely yes	
	Definitely no	

Abbreviations: LC, linkage coordinator; MARTAS, modified ARTAS; NA, no answer; SHCFs, specialized healthcare facilities.

<sup>a</sup>Data from one participant who reported 20 meetings with an LC has been excluded from the analysis; based on LC report, the total number of session with this participant was 6, other meetings with LC reported by the participant assumed were not related to MARTAS sessions and may happen during regular clinical visits of participant to SHCF.

while in ARTAS it was “at least one visit to an HIV clinician within a 6-month period.”

Study follow-up among participants who completed the 3-month interview—19 (86.4%)—was comparable with the ARTAS follow-up rate (86%).<sup>10</sup> The high level of participants’ satisfaction with their meetings with the LC and their opinion of their LC as knowledgeable about HIV confirms sufficient trust of the patients to the information delivered by healthcare providers, which justifies the proposed delivery of the intervention by nurses.

The ARTAS intervention has been adapted and implemented in several studies in different countries and populations.<sup>22–24</sup> One of the main modifications to the ARTAS in our study was delivery of the intervention not in community but in clinical settings.<sup>10</sup> Such approach fits well to the Ukrainian concentrated HIV epidemic<sup>25</sup> where key populations often seek medical care at specialty clinics. Referrals to psychological, addiction, and other services addressed the specific needs of key populations with HIV and multiple comorbidities.<sup>8,26</sup>

The study had certain limitations. Modified ARTAS was conducted at the clinical sites located in one region of Ukraine, so the results may not be generalizable to other settings. However, the centralized healthcare infrastructure makes this limitation less significant.

## Conclusion

Findings from this pilot study of the MARTAS intervention demonstrate the feasibility and acceptability of the proposed case management MARTAS intervention for adults recently diagnosed with HIV in selected specialty clinics. The results provide the rationale for a large-scale RCT to assess the effectiveness of the MARTAS intervention to link HIV-positive adults to HIV care in Ukraine.

## Authors’ Note

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the funding agencies. The study was approved by the internal review board at the Ukrainian Institute on Public Health Policy (FWA00015634) (approval no. 1, February 10, 2014) and the Science Integrity Branch of the CDC in Atlanta (tracking no. 2014-155, July 10, 2014). All participants provided written informed consent prior to enrolment in the study.



## Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

## Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This project has been supported by the President’s Emergency Plan for AIDS Relief (PEPFAR) through the US Centers for Disease Control and Prevention under the terms of grant 3U01GH000752-02S1.

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