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Conducting high-frequency data collection in low-resource settings: Lessons from a financial diary study among women engaged in sex work in Uganda

Lyla Sunyoung Yang^a, Susan S. Witte^a, Joshua Kiyingi^{b,c}, Josephine Nabayinda^{b,c}, Edward Nsubuga^c, Proscovia Nabunya^b, Ozge Sensoy Bahar^b, Larissa Jennings Mayo-Wilson^d, and Fred M. Ssewamala^b

^aSchool of Social Work, Columbia University, New York, NY, USA; ^bBrown School, Washington University in St. Louis, St. Louis, MO, USA; ^cInternational Center for Child Health and Development, Masaka Field Office, Masaka, Uganda; ^dDepartment of Health Behavior, Department of Maternal and Child Health, Gillings School of Global Public Health, University of North Carolina, Chapel Hill, NC, USA

ABSTRACT

Poverty and economic insecurity are driving forces in entering sex work among women in low resource areas. This increases their risk for HIV by influencing the decision-making process for high-risk behaviors. Few studies have examined the financial behaviors and capacities of women engaged in sex work (WESW). This paper describes the methodology used in a financial diary study aimed at characterizing women's spending patterns within a larger prevention intervention trial among WESW in Uganda. From June 2019 to March 2020, a subsample of 150 women randomized to the combination HIV prevention and economic empowerment treatment was asked to complete financial diaries to monitor daily expenditures in real time. Two hundred and forty financial diaries were distributed to study participants during the financial literacy sessions at eight sites. A total of 26,919 expense entries were recorded over 6 months. Sex-workrelated expenses comprised approximately 20.01% of the total. The process of obtaining quality and consistent data was challenging due to the transient and stigmatized nature of sex work coupled with women's varying levels of education. Frequent check-ins, using peer support, code word or visuals, and a shorter time frame would allow for a more accurate collection of high-frequency data. Moreover, the ability of women to complete the financial diaries despite numerous challenges speaks to their potential value as a data collection tool, and also as an organizing tool for finances.

KEYWORDS

Financial diary; sex work; poverty; Uganda; female sex worker; women engaged in sex work

Introduction

Poverty is the most-cited reason for involvement in commercial sex work in sub-Saharan Africa (SSA) (Fielding-Miller et al., 2014; Hargreaves et al., 2002). Gender inequalities have influenced women's social, economic, and political opportunities, making them more disadvantaged than their male counterparts (Aikman et al., 2008; Krishnan et al., 2008). In Uganda, where poverty and unemployment rates are disproportionately high among women (Gysels et al., 2002) transactional sex is a survival strategy (Stratford et al., 2008).

Social structural factors, such as the stigma, violence, cultural issues (Koenig et al., 2004), and criminalization of sex work (Schulkind et al., 2016), significantly influence human immunodeficiency virus (HIV) infection risks among women engaged in sex work (WESW) and their clients in Uganda.

WESW in SSA remain at highest risk for HIV. In Uganda, the HIV prevalence rate among WESW is 12 times higher than that of the general adult population. In some regions, including Rakai and Masaka, HIV prevalence among WESW is as high as 61% (Ssembatya et al., 2015; Vandepitte et al., 2011). For many women in this region, living with HIV or not, economic insecurity is a powerful driver to initiate sex work. But the need to rely upon sex work for income further exacerbates their vulnerability to HIV by influencing the decision-making process for high-risk behaviors (e.g., increase in number of sexual partners or sexual acts to earn more money) and compromises their ability to negotiate safe sex (more money is offered for unprotected sexual acts) (Karamouzian et al., 2016; Namey et al., 2018; Scorgie et al., 2012). Evidence-based microfinance to enhance HIV prevention may better address structural factors that hinder traditional prevention efforts for WESW (Awungafac et al., 2017; McCrimmon et al., 2018; Shannon et al., 2018; Witte et al., 2015, 2022).

As research examining combination economic empowerment and HIV prevention among WESW grows, there is a paucity of research, including data collection methods, that examine WESW's finances and financial behaviors (e.g., use of financial services and spending patterns) that could inform novel approaches to such structural-level, economic strengthening interventions (Blankenship et al., 2006; Namey et al., 2018; O'Malley & Burke, 2017; Swann et al., 2019). As active participants in the informal labor market, WESW have unique capabilities and needs that should be considered and incorporated into more innovative interventions targeting economic drivers of the HIV epidemic (Yang et al., 2021). Financial diaries, a high-frequency data collection methodology, can be used to gather daily financial transactions that, taken together, offer a comprehensive overview of individuals' financial lives and behaviors (Morduch & Siwicki, 2017). This method was first tested in low-resource countries such as Bangladesh, India, and South Africa among populations with a range of literacy and numeracy skills (Collins et al., 2009) and has since been utilized by individuals characterized as low-income or financially vulnerable in the United States and the United Kingdom (Biosca et al., 2020; Morduch & Siwicki, 2017). By tracking and gathering individual's financial transaction data including their earnings, savings, debts, and spending, financial diaries can provide insight into economic well-being and promote financial literacy among participants (Anderson & Ahmed, 2015; Rutherford, 2002). Financial diaries have been used in low-income contexts to understand financial behaviors and preferences within a population, to examine financial patterns related to specific issues (e.g., adherence to prevention of mother-to-child transmission care), or to assess changes in financial behaviors overtime (Collins, 2008; Lorenzetti et al., 2021; Tsai, 2017).

There are numerous methodological challenges to obtaining accurate and extensive financial data from WESW such as the criminalized nature of sex work, pervasive stigma toward sex work, and high mobility and low literacy levels among women engaged in sex work. For example, illegality of sex work leads to difficulties in obtaining a representative sample and concerns regarding privacy may lead individuals to refrain from sharing truthful answers (Shaver, 2005). This method of intense, high-frequency data collection is more challenging among highly transient and vulnerable populations, such as WESW, where repeated contact with participants may be difficult and where literacy levels are

low (Chang, 2017; Ferguson et al., 2006). An exploratory financial diary study among 33 WESW for 6 weeks in Abidjan, Côte d'Ivoire, reported that women were highly engaged in the financial diary activity and found it beneficial despite having limited literacy and numeracy skills (Namey et al., 2018). However, the authors did not elaborate on challenges experienced by the participants nor the research team. Furthermore, financial diary studies in low-resource settings have relatively small sample sizes and short data collection periods that may limit generalizability and not be able to account for seasonal volatility (Namey et al., 2018; Swann et al., 2019). They are also based on self-reported data, which may result in over- or under-reporting of financial transactions and impact accuracy (Morduch & Siwicki, 2017).

Despite the emphasis on the importance of ongoing data checks and frequent reminders to ensure quality control of the financial diary data, current published studies lack details regarding methodological challenges as well as specific recommendations for improvement or successful implementation of the method (Lorenzetti et al., 2021; Namey et al., 2018). Method-based studies that delineate the development, implementation, and lessons learned for obtaining high-frequency data collection among marginalized groups in low-resource settings are needed (Beegle et al., 2012). To fill this gap in literature, this paper describes the methods used in a financial diary study that aimed to characterize women's spending patterns within a larger combination intervention trial, testing the use of unconditional matched savings among WESW in Uganda (Ssewamala et al., 2019). To our knowledge, the current study is the first financial diary study to be implemented in Uganda and the largest to be conducted with WESW.

Methods

Research site and study population of parent study

The present financial diary study took place in the context of a larger randomized clinical trial being conducted in Uganda funded by the National Institute of Mental Health (R01MH116768). The trial seeks to evaluate the efficacy of an innovative combination HIV-prevention and asset-based microfinance intervention among WESW using a cluster-randomized controlled trial (Ssewamala et al., 2019). All study procedures were approved by the Washington University in St. Louis Institutional Review Board (IRB #201811106), Columbia University IRB (IRB #AAAR9804), and the in-country local IRBs in Uganda: Uganda Virus Research Institute (UVRI #GC/127/18/10/690) and the Uganda National Council of Science and Technology (UNCST #SS4828).

Between June 2019 and March 2020, 542 participants were recruited from 33 HIV hot spots in the southern region of Uganda. Eligibility of participants were assessed through a screening tool to determine if they met the following criteria: at least 18 years old, report having engaged in vaginal or anal intercourse in the past 90 days in exchange for money, alcohol, or other goods, and to report at least one episode of unprotected sexual intercourse in the past 90 days with either a paying, casual, or regular sexual partner. Outcome measures are collected at baseline, 6, 12, 18, and 24 months post-intervention (Ssewamala et al., 2019).

The parent study was originally designed with three study conditions: 1) HIV Risk Reduction (HIVRR) only as a control arm; 2) HIVRR plus Savings plus Financial Literacy (HIVRR + S + FL) treatment arm; and 3) HIVRR plus S plus FL plus

Vocational Skills Training and Mentorship (V) (HIVRR+S+FL+V) treatment arm. Detailed information on the design of the RCT and detail regarding the intervention components can be found in the protocol paper (Ssewamala et al., 2019). Due to the outbreak of the COVID-19 pandemic, we were limited in the ability to deliver the vocational training. Therefore, the study was reduced to only two conditions, with the control group receiving four sessions of HIVRR and the treatment intervention group receiving four sessions of HIVRR, six Financial Literacy sessions, and a matched savings account (Nabunya et al., 2021).

HIVRR was provided twice per week for 2 weeks, addressing important information and skills related to HIV transmission, condom use, condom use negotiation, linkage to preexposure prophylaxis and antiretroviral therapy medication adherence skills, and building social support. Women in the treatment condition additionally received six sessions of financial literacy training, which covered the importance of savings, banking services, budgeting (including household budget development), and debt management. Savings accounts were opened up for treatment condition participants at a local bank in the study area where women can make deposits. The intervention matched the amount the women saved at a rate of 1:1 to encourage savings and investment in small business enterprises (Ssewamala et al., 2019). The funds from the savings account could be used without any restrictions by the women. This unconditional aspect of matched savings was a unique adaptation to the intervention from previous versions (McCrimmon et al., 2018; Witte et al., 2011). It was chosen in order to honor women's decisions related to how best to support themselves and their families without presuming that conditioning the matched savings on purchases related to a shift in education or vocation would necessarily lead to reduced HIV/ STI risk behaviors. Thus, the financial diary component was utilized to better understand the spending patterns of WESW.

Financial diary data collection & tools

Intervention facilitators introduced financial diaries to participants in the second session of the FL sessions. They described the purpose of the diaries and how to complete them. English and Swahili language versions of the booklets were available for use. A total of 150 women from eight sites received the first round of financial diaries. The research team trained participants on how to record their expenses through one-on-one meetings where the participants could ask questions about the process. They were encouraged to fill out the financial diaries daily. A financial diary had entries for a date, description of an item bought, and amount spent (Figure 1). Participants were asked to record expenses daily in real time in Ugandan shillings. The exercise was intended to last for 10 months (during the intervention period), with check-in meetings scheduled monthly to review the diaries.

There is limited published information regarding the reliability and validity of financial diaries. The method is open to many challenges because it involves individuals self-recording their daily financial transactions consistently and accurately throughout a designated period (Lucey, 2005). Researchers have used various approaches such as weekly face-to-face interviews, tablet data collection for real-time uploads, and practice periods for participants as well as data collectors to enhance reliability (Lorenzetti et al., 2021; Swann et al., 2019).

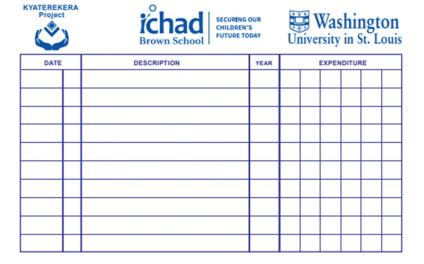


Figure 1. Financial diary page.

Financial diary review

For quality assurance and monitoring, monthly meetings were convened following the completion of the FL sessions. This involved having research team members review entries with WESW, clarifying those that were unclear. The research team would then sign each financial diary to confirm the review and where to begin at the following visit. Initial meetings could last between 3 and 4 hours depending on WESW's availability, but over time reduced considerably in duration to up to 30 minutes if women needed additional support. Due to the outbreak of COVID-19 in Uganda in March 2020, most of the study field activities were suspended, which affected the continuation of financial literacy sessions and the in-person monthly review of financial diaries. Data for this paper include the first 6 months of the financial diary data before the COVID-19 lockdown went into place.

To increase the reliability of the financial diaries, the research team followed a routine procedure for reviewing and collecting the financial diary data. First, the research team contacted the study participants to schedule meetings with them at designated study sites. Second, on the review day, the research team took attendance of WESW, provided a recap of how to complete a financial diary, and addressed additional questions regarding the research process. Third, members of the research team then met one-on-one with each WESW to review their completed financial diaries where the researcher took pictures of all the entries and signed the last page. The sites with more active peer leaders sometimes volunteered to review financial diaries prior to WESW meeting with the research team. Fourth, the researcher collected the finished financial diaries, as applicable, and gave out new ones. The collected financial diaries were kept under a double locked cabinet in the study team's office. Finally, the next review session was scheduled at the end of the check-in.

Financial diary data entry process & analysis

The expenses recorded in the financial diaries were entered in Microsoft Excel as they appeared (date, description, amount spent). Guided by other financial diary studies (Collins et al., 2009; Swann et al., 2019) and by common descriptors, the data were then recoded into 15 categories which included food and beverages, housing/lodging, cosmetics and salon, toiletries, clothing and beddings, communication, transportation, education, health and medical, savings and investigates, kitchenware, utilities, leisure/entertainment, drugs, and other expenses. For each participant, the data were summarized, showing total expense per category for a given month. Expenses were reported in Ugandan shillings (UGX) to the nearest shilling and in United States dollar (USD) to the nearest cent. Descriptive statistics were utilized to provide simple summaries using SPSS (version 26) for sample characteristics and excel for the expenses.

Results

Sample characteristics

A total of 150 WESW completed financial diary reviews between October 2019 and March 2020 (see Table 1). At study enrollment, WESW's ages ranged from 18 to 55 years, with a mean age of 32.2 years (SD = 7.9). Of the sample, 66% of WESW reported being divorced/separated or widowed, while 22% of the WESW reported being in a relationship or in a marriage. Half of the WESW (49.4%) completed Primary 7 or less in education, and a slightly smaller proportion of WESW (40.7%) reported having completed Primary 7 to Senior 6. Most WESW (68.7%) reported being the highest income earner in their household with a mean of 178,266.67 shillings (~49.91 USD) in individual monthly income and 268,573.33 shillings (~75.20 USD) in household monthly income. The vast majority of WESW (80%) operated their sex work without a boss or manager.

Table 1. Baseline demographics of WESW (N = 150).

Variable	Percentage (n)
Age (mean, range)	32.2 (18–55)
Marital status	(,
Divorced/separated or widowed	66.0% (99)
Married or in a relationship	22.0% (33)
Single, never married	12.0% (18)
Education	
Did not attend school	9.3% (14)
Primary 7 or less	49.4% (74)
Senior 6 or less	40.7% (61)
Technical/vocational college diploma	.7% (1)
Highest household income earner	
Respondent	68.7% (103)
Husband, boyfriend, or other primary partner	14.0% (21)
Another adult and other	17.3% (26)
Total monthly household income in UGX (mean, SD)	268 573.33 (214 184.28)
Total monthly participant income in UGX (mean, SD)	178 266.67 (151 258.69)
Do not have a boss or manager for sex work	80.0% (120)

Table 2. Monthly financial diary entries and total expenses.

	Total # of entries	Mean expense UGX (~USD)	Median expense UGX (~USD)
October 2019	47	27,972 (7.83)	3,000 (0.84)
November 2019	2,185	5,589 (1.57)	2,000 (0.56)
December 2019	6,236	5,717 (1.60)	2,000 (0.56)
January 2020	5,039	5,545 (1.55)	2,000 (0.56)
February 2020	6,884	5,494 (1.54)	1,800 (0.50)
March 2020	6,528	4,293 (1.20)	1,500 (0.42)

Note: 1 Ugandan shilling to .00028 USD

Table 3. Breakdown of expenses by category.

	Total Amount UGX	Equivalent in USD	% of All Expenses
Food & Beverages	65,495,760	18,338.81	42.75%
Sex-Work-Related Expenses:	30,650,400	8,582.11	20.01%
Lodging	434,500	121.66	0.28%
Cosmetic & Salon	5,591,600	1,565.65	3.65%
Clothing	13,763,800	3,853.86	8.98%
Transport	5,742,400	1,607.87	3.75%
Communication	5,118,100	1,433.07	3.34%
Housing	14,735,499	4,125.94	9.62%
Toiletries	3,413,300	955.72	2.23%
Education	9,802,900	2,744.81	6.40%
Health & Medical	7,392,500	2,069.90	4.83%
Investments & Savings	6,001,600	1,680.45	3.92%
Kitchenware	2,417,700	676.96	1.58%
Utilities	2,693,400	754.15	1.76%
Leisure & Entertainment	2,872,000	804.16	1.87%
Drugs	2,000	0.56	0.00%
Other	7,714,800	2,160.14	5.04%
Total	153,191,859	42,894	100%

Monthly financial diary expenses

Table 2 provides basic summary statistics for WESW's involvement in the financial diary data collection. A total of 240 financial diaries were distributed to WESW during the financial literacy sessions at eight sites. During the 6-month data collection period, a total of 26,919 expense entries were recorded, with a median amount between 1,500 UGX (~0.42 USD) to 3,000 UGX (~0.84 USD). The mean amount for the first month was unusually high due to the low number of expense entries.

Description of expenses

Table 3 provides a breakdown of WESW's expenses by category. The biggest portion of the total expenses went to purchasing food and beverages (42.75%). During the check-in meetings, WESW shared with the research team that the lodging expenses ranging from 10,000 to 12,000 shillings (2.84–3.40 USD) were for sex work. Women opted to rent lodging to take clients in order to hide their occupation from family members and friends. Some of the amount from housing could also be attributed to sex work because some WESW described conducting sex work in their homes, but the exact amount could not be separated out, meaning that the 20% of sex work expenses may be an underestimate. Moreover, WESW shared that most of their expenses related to cosmetics, salon, clothing, communication, and transportation were specific to sex work. Sex-work-related expenses therefore

comprised 20.01% of total expenses. Other expenses included housing (9.62%), education (6.40%), and medical (4.83%). Only 1.83% of the total expense was spent on leisure and entertainment.

Discussion

This financial diary study was among the first and largest to examine the feasibility of using this method to capture the spending patterns of WESW in SSA. The greatest proportion of total reported expense was for fulfilling basic daily needs such as food, beverages, and housing. Our study also estimates that approximately 20% of the expenses were related to conducting sex work. These results were similar to another financial diary study conducted with WESW in Côte d'Ivoire where participants spent 22% of their income on food and nearly 30% on sex-work-related expenses (Namey et al., 2018). Namey et al. (2018) included exit interviews with the participants that illustrated the usefulness of financial diaries in changing their perceptions of money and encouraging financial management strategies. Complimenting financial diary study with a qualitative component would be beneficial to provide richer context and meaning regarding participants' financial lives.

Due to the transient nature of sex work, varying levels of education of WESW, coupled with the natural disasters (heavy rainfall and flooding) that occurred in southwestern Uganda during the data collection period, the process of obtaining quality, complete, and consistent data was challenging. Given these risks to data quality and reliability, the research team applied numerous techniques and made adaptations to overcome the barriers. We found that fewer WESW recorded their expenses in the first 2 months of starting the financial diary data collection. The number of entries grew significantly over time, presumably as WESW became more familiar with diaries and the research team employed various strategies to increase entries and accuracy. There were multiple reasons for the minimal participation in the beginning. Some WESW expressed fear around how their financial information would be used. Due to the criminalization of sex work in Uganda (Ellis, 2021), many of the WESW were hesitant to reveal any information that might connect them to sex work. Therefore, expenses specifically related to sex work could only be estimated based on what the WESW shared verbally with the research team during the check-ins.

Another reason for lack of engagement was that some WESW did not know how to read or write and therefore had difficulties writing down their daily expenses. Similar challenges documented in another financial diary study conducted among pregnant women and new mothers in Lorenzetti et al. (2021) also recorded this phenomenon, and because of inconsistent data, they considered the first 4 weeks of the financial diary data collection period as a learning period for both the WESW and data collectors. This period was used to build confidence in the quality as well as accuracy of the data to be collected, and data from these 4 weeks were excluded from the final analysis (Lorenzetti et al., 2021).

With support through monthly phone calls by the research team, WESW steadily increased the number of data entries. Monthly check-ins served as a constant reminder and a source of encouragement for the WESW to continue capturing their daily expenses. The sites with more active peer leaders showed higher engagement among WESW as the peers volunteered their time to review the financial diaries before check-in meetings and boosted women's confidence. Other studies have utilized monetary or other incentives to

increase participation. For example, in a participatory geographic mapping study in the Dominican Republic among WESW, the researchers utilized an incentive-based completion strategy where compensation increased on a per item-completed basis in the travel diary to track women's daily routes, which they reported was useful and minimized participant drop-out (Felker-Kantor et al., 2021). WESW, with low literacy levels in our study, were encouraged to ask for support from family and friends in filling out the expenses. However, some WESW found it challenging to record transactions related to sex work when working with family and friends.

Participants who completed the financial diaries were also negatively impacted by environmental disasters and life circumstances during data collection. Multiple floods that occurred in 2020 in towns near Lake Victoria destroyed WESW's homes and their belongings, including the financial diaries. Furthermore, WESW in Uganda are highly mobile due to a myriad of factors such as employment opportunities, violence, and lack of familial support (King et al., 2021). The WESW in our study also moved frequently and often misplaced their financial diaries. Filling out the financial diary everyday with financial transactions for an extended period of time is a burdensome task for WESW, particularly for those who are living in precarious living situations. Shorter data collection time frames such as 2 weeks or a month may be more feasible for transient populations in order to ensure higher participation and thus accuracy of the financial lives of the participants. In a related diary study, Felker-Kantor et al. (2021) asked participants to send a daily snapshot of their completed travel diary and sent daily reminders via the free messaging service WhatsApp. This approach yielded a high response rate of 87% during a 7-day data collection period with no travel diaries lost.

Overall, financial diaries have been shown to be a valuable tool for measuring and providing insights into financial patterns of its participants. To enhance the validity of financial diaries as a measurement tool, diary data can be triangulated with results from other qualitative or quantitative methods. For example, researchers in the US Financial Diaries study tracked inconsistencies in data by checking diary data against bank statements, tax forms, and follow-up interviews with participants (Morduch & Siwicki, 2017).

Recommendations to improve implementation of financial diaries

We held a debriefing session with the research team in Uganda about the process of implementing the financial diary study to discuss strengths and weaknesses of the approach in order to develop recommendations for future work of this kind. The first recommendation was to introduce the financial diaries in the first or second FL sessions to provide early exposure to how it works and why it may be helpful in managing finances. Financial diaries could be integrated as part of the FL curriculum as an activity to do at home and receive feedback from FL facilitators in subsequent sessions. A second recommendation was to increase the frequency of check-ins and reminders with the participants to minimize recall bias. Similar to antiretroviral therapy medication adherence interventions, text messaging could be used as quick and low-cost reminders for the participants to remember to fill in their financial dairies that day (Whiteley et al., 2021). A third recommendation built on the unplanned phenomenon of peer mobilizers volunteering to help the participants who were having trouble with financial diaries. The participants benefited greatly from receiving on-demand support

and getting their questions answered by peer mobilizers before or after FL sessions when they were already at the intervention sites. Therefore, it was recommended that peer mobilizers be incorporated for all sites to assist the research team in collecting financial diary data and providing technical support. Moreover, WESW expressed their hesitancy about recording transactions related to sex work when they were receiving help on completing the financial diaries from family or friends. Peer mobilizers may be a nonstigmatizing source of support, particularly for participants who have not shared their sex work with family or friends. Additionally, the research team suggested offering code words or visuals for capturing sex work-related expenses in order to be able to record accurate data without putting participants in danger or discomfort.

WESW's ability to complete the financial diaries in spite of numerous challenges speaks to the potential value they hold both as a data collection tool but also as an organizing tool for finances. In Community Collaborative Board meetings, some women shared that they found the process of completing the tool reinforcing of what they learned in the FL sessions and that it strengthened their interest in savings and in economic empowerment activities.

Limitations

This study has several limitations. First, as seen in Table 2, the number of recorded entries is very low during the first and second months. Large amounts of missing data may lead to inaccurate and underrepresented overview of the financial snapshot of the participants. More careful preplanning is needed to ensure active participation in a high-intensity data collection method such as the financial diaries. Second, given the high level of sex work stigma and the nature of self-reported data, it is possible that there may be recall bias and/or information bias. The financial diary findings on WESW's financial affairs may have limited generalizability. However, the focus of this paper was to provide a detailed description of the methodology used and to offer lessons learned to fill the gap in addressing methodological challenges for collecting high-intensity data among WESW.

Conclusion

This study demonstrated that financial diary methodology has the potential to provide a comprehensive and contextualized understanding of financial affairs of WESW, which may help inform targeted intervention strategies for this unique population with varying levels of financial capabilities. Despite numerous challenges to obtain such high-frequency data from a transient population, the methods described here and recommendations from the financial diary implementers can be used to improve researchers' capacity to collect higher quality financial data among populations in limited resource settings.

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Author contributions

FMS and SSW conceived the study and are the principal investigators. FMS, SSW, PN, and OSB developed the study protocol with contributions from JK and LJMW. EN and JN coordinated study tasks and data collection. JK coordinated financial data management and categorized all FD entries. LSY conceived the manuscript, organized the data, and prepared all data tables and figures, with assistance from JN and JK, and prepared the first draft of the manuscript. JK, OSB, LJMW, SSW, and FMS contributed to interpreting the data and editing the manuscript as needed. All authors have read and approved the final manuscript.

Data availability statement

Restrictions apply to the availability of these data due to the sensitive nature of the research. Requests may be made to the principal investigator, FMS.

Disclaimer

NIMH had no role in the study design, data collection, analysis, interpretation of findings, and preparation of this manuscript. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH. Clinical trial registration: ClinicalTrials.gov NCT03583541.

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