A Randomized Controlled Trial to Determine the Effect of Dispensing Blister and Traditional Loose Packaged Iron-Folic Acid Supplements on Adherence Measured by Count on Next Return Visit and Hemoglobin Levels among Pregnant Women at Mulago and Kawempe National Referral Hospitals in Kampala, Uganda

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KEY TAKE-AWAY

Blister packaging has no effect on iron-folic acid adherence among pregnant women, although hemoglobin levels were higher.

BACKGROUND/OBJECTIVE

Anemia in women 15–49 years is a global public health problem, with consequences of maternal, neonatal, and child mortality; low birth weight; impaired child development; fatigue; and low productivity. The 2018/2019 Uganda National Panel Survey (UNPS), estimates 17 percent of non-pregnant women and 14 percent of pregnant women are anemic, an improvement from 38 percent in the 2016 Uganda Demographic Health Survey (UDHS) among pregnant women. UNPS estimates that 22 percent and 6 percent of pregnant women have iron deficiency and iron deficiency anemia, respectively. However, the 2016 UDHS reported only 23 percent of pregnant women received 90 or more iron-folic acid (IFA) supplements, and 1 percent received 180 or more. No researchers have conducted trials to assess the effectiveness of IFA blister and loose packaging on adherence to treatment in Uganda.

METHODS

Between April and October 2016, we randomized 952 pregnant women at ≤28 weeks attending antenatal clinic (ANC) to receive IFA supplements in either blister packs (intervention arm=478) or loose (control arm=474).

Participants completed baseline hemoglobin measurements and received 30 IFA supplements at enrollment. Researchers assessed adherence by pill count and measured hemoglobin at four and eight weeks. The results were presented using both intention-to-treat and per-protocol analysis.

The study was non-blinded for participants and the research team. Loss to follow-up was high.

Key informant interviews with health workers and focus group discussions with pregnant women to understand the perception to the study, barriers, enablers, and whether packaging influences IFA intake backed up the results.

Mother illustrates IFA intake after the lesson with the midwife.
Photo Credit: SPRING Uganda

RESULTS

There were 474 participants in the control and 478 in the intervention arm, respectively. There was no significant difference in participant adherence between those receiving IFA from blister and loose packaging at the fourth week (45.0 and 45.9 percent, p=0.88) and eighth week (60.3 and 51.2 percent, p=0.24). However, the percentages were higher among those who took the blister packs, as seen in tables 1 and 2.

Table 1. Adherence to IFA at First Visit (4th Week) and Second Visit (8th Week) Analysed by Intention to Treat

Characteristics	IFA in Blister Packaging n=478	IFA in Loose Packaging n=474
First follow up visit or return visit (week 4)		
Participants who returned for first follow up visit	361	355
Participants who returned within 30 days [n (%)]	250 (52.3)	242 (51.1)
Balance of pills counted on first return visit [mean ± standard deviation (SD)]	3.5 ± 3.9	3.5 ± 4.6
100% adherence among participants on first return visit [n (%)]	194 (40.6)	185 (39.0)
90% adherence among participants on first return visit [n (%)]	220 (46.4)	220 (46.0)
Second follow up visit (week 8)		
Participants who returned for followed up at second visit (8 week)	301 (60.3)	271 (55.3)
Balance of pill count on second return visit [mean ± SD]	2.6 ± 3.3	2.9 ± 3.7
100% adherence among participants on second return visit [n (%)]	248 (51.9)	222(46.8)
90% adherence among participants returning on second visit [n (%)]	286 (59.8)	268 (56.5)

We observed no significant difference in hemoglobin levels between the blister and loose packaging groups at the fourth week (p=0.26) and eighth week (p=0.36), respectively. However, over the eight-week period the blister package group had a higher change in hemoglobin (0.6±1.0) compared to the loose packaging group (0.2±1.1) with a difference of 0.4g/dL (95 percent confidence interval: 0.24–0.51g/dL); p=0.001.

Researchers lost contact with 380/952 (39.9 percent) women during follow up—42.8 percent in the control arm and 37.3 percent in the intervention arm—possibly due to relocation from Mulago to Kawempe Hospital.

Health workers educated participants on the benefits and side effects of IFA intake during ANC visits. Holding mothers accountable by counting remaining pills during ANC revisits was reported to have played a major role in adherence, despite the side effects of IFA.

Table 2. Adherence to IFA at First Visit (4th Week) and Second Visit (8th Week) Analysed per Protocol

Characteristics	IFA in Blister Packaging	IFA in Loose Packaging
First follow up visit or return visit (week 4)		
Participants who returned for first follow up visit	361	355
100% adherence among participants on first return visit [n (%)]	194 (53.7)	185 (52.1)
Second follow up visit (week 8)		
Participants who returned on second (8 week) follow up visit	302 (60.3)	271 (55.3)
Balance of pill count on returned visit [mean ± SD]	2.2 ± 2.8	2.6 ± 3.2
100% adherence on second return visit [n (%)]	199 (66.0)	159 (58.7)

CONCLUSIONS/FINDINGS

Study findings showed that blister packaging had no effect on eight weeks of adherence to IFA supplementation regimens among pregnant women attending the ANC in two hospitals in Uganda. The intervention group had higher hemoglobin levels compared to control group over the eight weeks.

Providing education on the benefits of IFA intake and counting of remaining pills by health workers during ANC visits was reported to have played a major role in adherence.

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