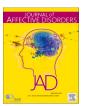
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## Correspondence



Alterations in sample selection and low adherence to psychotherapy manuals lead to unexpected results. A letter to the Editors on "Randomized controlled trial for the Attempted Suicide Short Intervention Program (ASSIP): An independent non-replication study"

Dear Editors,

In their recent publication in this journal, Monn et al. (2025) sought to independently replicate the attempted suicide short intervention program (ASSIP) study (Gysin-Maillart et al., 2016). We appreciate the effort of the authors, as replication is critical for confirming efficacy and identifying contextual factors influencing outcomes (Cuijpers, 2017; Ioannidis, 2005). However, three significant methodological deviations suggest that Monn's study was not designed to replicate ASSIP: subject selection, choice of the primary outcome, and adherence to the ASSIP manual were substantially different from the original trial. Instead, authors tested a variation of ASSIP in a quite distinct sample.

First, the Zurich sample included participants of greater clinical complexity than the original cohort. Rates of comorbid substance abuse (48 % vs. 17 %), personality disorders (35 % vs. 13 %), and multiple past suicide attempts (39 % vs. 17 %) were substantially higher in the replication trial. This selection includes more individuals at elevated risk for future suicidal behavior with difficult-to-treat courses who might be less responsive to brief interventions (Arvilommi et al., 2022; Conner et al., 2021; Owens et al., 2002). Overall, compared to the original study, the new study sample had approximately three times higher rates of comorbid substance use and prevalence of personality disorders, while rates of past suicide attempts were doubled. Thus, the new sample included substantially more severe cases.

Notably, Gysin-Maillart et al. (2022) identified a subgroup of ASSIP participants with persistently high "Reasons for Dying" scores over 24 months—the so-called "Steady High" group. This group had the highest number of past and future suicide attempts (mean past attempts: 2.62; mean reattempts during follow-up: 1.67), elevated depression scores (mean BDI: 28.66), and the highest rate of F6 diagnoses (42.9 %). This suggests that individuals with the most severe and persistent risk profiles may either drop out or not fully engage with the intervention—raising the concern that a similar imbalance might have occurred in the replication study, possibly biasing the per-protocol analysis toward non-responders.

Second, Monn et al. used a binary primary outcome (occurrence of at least one suicide attempt within 12 months), diverging from the time-to-event outcome from a survival analysis used to assess the time to first suicide attempt over 24 months in the original study. Survival analysis takes into account critical information about the timing of the event, enhancing power and clinical interpretability (Nosek and Errington, 2020). In contrast, the binary endpoint reduces statistical power and does not account for participants who remained event-free for long periods before dropping out. To illustrate the extent of the difference in outcomes, the original ASSIP trial reported a 79 % reduction in the risk of repeat suicide attempts over 24 months (Gysin-Maillart et al., 2016),

whereas the new study found no significant difference between the intervention and control groups after 12 months.

Finally, authors failed to monitor treatment fidelity systematically. Therapist adherence and competence of ASSIP (ACS-ASSIP; Gysin-Maillart et al., 2019, 2025), describing the five core elements of the method, were not assessed, nor supported by mandatory video-based supervision of sessions (2 and 3). Moreover, one therapist treating seven patients in the intervention arm of the replication study was incorrectly described as certified. However, therapist certification in an intervention method is a core quality requirement for replication studies. In fact, the NIH Behavior Change Consortium defined treatment fidelity to enhance the reliability and validity of behavioral interventions (Bellg et al., 2004; Boutron et al., 2008). Key dimensions of fidelity include proper training, treatment delivery, receipt, and enactment (Borrelli, 2005, 2011), some of which were not met by Monn et al.

What can be learned from this study is that delivering a slightly different version of ASSIP to a more severely ill sample of patients falls short of achieving a strong effect. Monn et al. faced a number of challenges, particularly during the pandemic. They included fewer participants than planned. In addition, about one-third of the participants did not complete the three intervention sessions. These core sessions are essential to ASSIP's therapeutic model. The per-protocol analysis was conducted on only 26 intervention completers, limiting robustness. Furthermore, it remains unclear how many of these received the full sequence of follow-up letters, a crucial intervention element. While the original ASSIP trial secured continuous supervision to ensure methodological rigor and prevent therapist drift (Waller, 2009), supervision of the psychotherapists was not part of Monn's trial.

Monn et al. also compare their findings to other studies using ASSIP. However, these trials had differing designs and were not aimed to replicate the ASSIP trial: the Finnish study (Arvilommi et al., 2022) compared ASSIP to an active crisis intervention, while the U.S. trial (Conner et al., 2021) implemented a 1–2-day inpatient version for patient with severe substance use disorders. These settings diverge significantly from the original outpatient protocol. A meta-analysis incorporating risk of bias and implementation fidelity is needed to clarify efficacy across contexts (Sterne et al., 2019). Low-fidelity replications risk obscuring intervention effects and may mislead meta-analyses and guidelines.

In conclusion, although we commend the effort of Monn et al. to examine ASSIP, substantial methodological deviations preclude the classification as a direct replication. The new study used a different primary outcome, had reduced fidelity, inconsistent supervision, and a smaller sample size in a sample of substantially higher illness severity (comorbid substance abuse, repeated attempts). These factors

contributed to the observed null or unexpected outcomes. However, this finding does not render ASSIP to be ineffective, instead it goes to demonstrate that ASSIP may not work in all settings or with less adherence to the manual.

Future trials are clearly needed. They should aim for standardized implementation with sufficient statistical power, robust fidelity monitoring, and population comparability. Ongoing RCTs in Sweden (Lindström et al., 2024) and the United States (Pisani et al., 2023) are expected to provide additional insights into when, how, and for whom ASSIP is most effective. High-quality replications, even when yielding negative results, are essential for advancing suicide prevention research.

#### CRediT authorship contribution statement

Anja C. Gysin-Maillart: Validation, Methodology, Conceptualization, Writing – review & editing, Writing – original draft. Sebastian Walther: Validation, Methodology, Conceptualization, Writing – review & editing. Sara Lindström: Validation, Methodology, Conceptualization, Writing – review & editing. Anna Ehnvall: Validation, Methodology, Conceptualization, Writing – review & editing. Laurent Michaud: Validation, Conceptualization, Writing – review & editing. Stéphane Saillant: Validation, Conceptualization, Writing – review & editing. Gregor Berger: Validation, Conceptualization, Writing – review & editing. Kristina Adorjan: Validation, Methodology, Conceptualization, Writing – review & editing. Simon Schwab: Validation, Methodology, Conceptualization, Writing – review & editing.

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## Declaration of competing interest

Two of the authors (A.G.M. and S.S.) were involved in the original ASSIP trial. Furthermore, A.G.M. wrote the ASSIP manuals. This experience formed the basis for the analysis of the method presented in this letter. The other authors declare no conflicts of interest.

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### References

- Arvilommi, P., Hautala, H., Riala, K., Oinas, E., 2022. Effects of the attempted suicide short intervention program on suicidal behavior: a randomized controlled trial. Crisis 43 (3), 215–223. https://doi.org/10.1027/0227-5910/a000790.
- Bellg, A.J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D.S., Ory, M., Ogedegbe, G., Orwig, D., Ernst, D., Czajkowski, S., 2004. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. Health Psychol. 23 (5), 443–451. https://doi.org/10.1037/ 0278-6133\_23.5\_443.
- Borrelli, B., 2005. The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. J. Public Health Dent. 65 (1), 52–58. https://doi.org/ 10.1111/j.1752-7325.2005.tb02817.x.
- Borrelli, B., 2011. The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. J. Behav. Med. 34, 54–67. https://doi.org/10.1007/ s10865-011-9353-z.
- Boutron, I., Moher, D., Altman, D.G., Schulz, K.F., Ravaud, P., 2008. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. Ann. Intern. Med. 148 (4), 295–309. https://doi.org/ 10.7326/0003-4819-148-4-200802190-00008.

- Conner, K.R., Pisani, A.R., Kemp, J.E., Adkins, E.C., Woodford, A.L., Miller, C.L., Tu, X. M., 2021. Randomized trial of post-attempt short interventions for reducing suicidal behavior among patients with substance use disorders. Psychiatr. Serv. 72 (12), 1437–1443. https://doi.org/10.1176/appi.ps.202000788.
- Cuijpers, P., 2017. The challenges of improving treatments for depression. JAMA 318 (3), 235–236
- Gysin-Maillart, A., Schwab, S., Soravia, L.M., Megert, M., Michel, K., 2016. A novel brief therapy for patients who attempt suicide: a 24-months follow-up randomized controlled study of the Attempted Suicide Short Intervention Program (ASSIP). PLoS Med. 13 (3), e1001968. https://doi.org/10.1371/journal.pmed.1001968.
- Gysin-Maillart, A., Conner, K., Pisani, A., Lindström, M., Westrin, Å., Ehnvall, A., 2019, 2025. ASSIP Adherence and Competence Scale (ASSIP ACS) [Unpublished Manual] (Originally developed in 2019; revised April 2025. Copyright © ASSIP ACS. All rights reserved).
- Gysin-Maillart, A.C., Jansen, R., Walther, S., Jobes, D.A., Brodbeck, J., Marmet, S., 2022. Longitudinal development of reasons for living and dying with suicide attempters: A 2-year follow-up study. Frontiers in psychiatry 13, 865831.
- Ioannidis, J.P.A., 2005. Why most published research findings are false. PLoS Med. 2 (8), e124.
- Lindström, S., Ehnvall, A., Bergqvist, E., Waern, M., Dahlin, M., Westrin, Å., 2024. A study protocol of the effectiveness of the Attempted Suicide Short Intervention Program (ASSIP) for recent suicide attempters: a randomized controlled trial. BMC Psychiatry 24 (1), 655. https://doi.org/10.1186/s12888-024-06109-z.
- Monn, A., Villar de Araujo, T., Rüesch, A., Kronenberg, G., Hörmann, C., Adank, A.,
  Roman, Z., Schoretsanitis, G., Rufer, M., Seifritz, E., Kleim, B., Olbrich, S., 2025.
  Randomized controlled trial for the Attempted Suicide Short Intervention Program (ASSIP): An independent non-replication study. J. Affect. Disord. 382, 59–67.
- Nosek, B.A., Errington, T.M., 2020. What is replication? PLoS Biol. 18 (3), e3000691. https://doi.org/10.1371/journal.pbio.3000691.
- Owens, D., Horrocks, J., House, A., 2002. Fatal and non-fatal repetition of self-harm: systematic review. Br. J. Psychiatry 181 (3), 193–199. https://doi.org/10.1192/bjp.181.3.193.
- Pisani, A., Connor, K., Van Orden, K., Jordan, N., Landes, S., Curran, G., McDermott, M., Ertefaie, A., Kelberman, C., Ramanathan, S., Carruthers, J., Mossgraber, K., Goldston, D., 2023. Effectiveness of a targeted brief intervention for recent suicide attempt survivors: a randomised controlled trial protocol. BMJ Open 13 (3), e070105. https://doi.org/10.1136/bmjopen-2022-070105.
- Sterne, J.A.C., Savović, J., Page, M.J., Elbers, R.G., Blencowe, N.S., Boutron, I., Cates, C. J., Cheng, H.Y., Corbett, M.S., Eldridge, S.M., Emberson, J.R., Hernán, M.A., Hopewell, S., Hróbjartsson, A., Junqueira, D.R., Jüni, P., Kirkham, J.J., Lasserson, T., Li, T., McAleenan, A., Reeves, B.C., Shepperd, S., Shrier, I., Stewart, L.A., Tilling, K., White, I.R., Whiting, P.F., Higgins, J.P.T., 2019. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ 366.
- Waller, G., 2009. Evidence-based treatment and therapist drift. Behav. Res. Ther. 47 (2), 119–127.
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