The Verona-Lugano Tool – VELUT

Preliminary questions	Response options
1. Indicate the outcome considered of this specific appraisal	Open question
2. Indicate the analytical sample of this specific appraisal	1. Whole analytical sample 2. Subsample
2b. Please describe the subgroup	Open question

Item	Label (score)
P1. Did study participants go through a screening process to be enrolled in the study? [1]	
All target individuals in the source populations are eligible and included (no selection / screening made)	Promotion / Univ. Prevention (-3)
Inclusion criteria were based on exposure to risk factors	Sel. Prevention (-1)
According to inclusion/ exclusion criteria, the planned study sample comprises participants with symptoms, but below a diagnostic threshold / clinical cut-off	Ind. Prevention (+1)
According to inclusion/ exclusion criteria, the planned study sample comprises participants with a formal diagnosis / above diagnostic threshold / clinical cut-off	Treatment (+3)
Unclear or insufficient information	NA
P2. How was the screening conducted? [2]	
No screening, or participants enrolled irrespective of screening/ selection results	Promotion / Univ. Prevention (-3)
With a risk factors assessment measure(s) (e.g., having a migration background, currently unemployed, currently pregnant)	Sel. Prevention (-1)
With a scale(s) for symptoms or functional impairment (with optimized cut-off; e.g., scoring above a threshold for psychological distress, or being distressed but scoring below a threshold indicating a clinical diagnosis)	Ind. Prevention (+1)
With a diagnostic tool(s) (e.g. positivity on structured clinical interview: SCID, MINI, Hamilton ecc.), or scoring above a symptom scale threshold indicating a clinical diagnosis	Treatment (+3)
Unclear or insufficient information	NA
P3. Were the study participants symptomatic at baseline based on an optimized cut-off? [3]	
All participants below a diagnostic threshold	Promotion / Univ. Prevention (-3)
A minority of participants above a diagnostic threshold/ clinical cut-off	Sel. Prevention (-1)
Most participants above a diagnostic threshold/ clinical cut-off	Ind. Prevention (+1)
All participants above a diagnostic threshold/ clinical cut-off	Treatment (+3)
Unclear or insufficient information	NA
I1. How was the intervention originally conceived and described, as outlined or implied in a manual, if available?	
Intervention primarily conceived for promotion / universal prevention (according to theory of change) (for example empowerment and/or information, education, skill development, and behavioral changes)	Promotion / Univ. Prevention (-3)
Intervention primarily conceived for selective prevention (for example, mainly about addressing or mitigating risk factors)	Sel. Prevention (-1)
Intervention primarily conceived for indicated prevention (for example, mainly about Stress-management; problem solving)	Ind. Prevention (+1)
Intervention primarily conceived for treatment (for example, structured psychotherapy with a manual, or treatment)	Treatment (+3)
Unclear or insufficient information	NA
I2. What was the timing of the intervention with respect to the exposure(s)?	
Intervention delivered to all independently from any exposures/events and/or contents of the intervention appropriate for the general population, regardless of if and when people were exposed to any event	Promotion / Univ. Prevention (-3)
Intervention delivered before/during the exposure/event and/or contents focused on coping mechanisms (or support, for example, housing or job hunting) for normal life stressors, and/or in preparation for potential future consequences of the event	Sel. Prevention (-1)
Intervention delivered after the exposure/event but before the onset of the mental health condition	Ind. Prevention (+1)
Intervention delivered after the exposure/event and after the onset of the mental health condition (assessed as either part of the study or independently)	Treatment (+3)
Unclear or insufficient information	NA
I3. In this specific RCT, what was the primary aim of the intervention?	
To improve overall wellbeing (physical, psychological, social)	Promotion / Univ. Prevention (-3)
To target modifiable risk factors, social determinants, or exposures	Sel. Prevention (-1)
To reduce subclinical symptoms and/or distress/to prevent the development of a condition	Ind. Prevention (+1)
To treat a specific condition	Treatment (+3)
Unclear or insufficient information	NA
O1. Which was the considered outcome?	
Wellbeing / knowledge and understanding / 'change in attitudes' or similar outcome	Promotion / Univ. Prevention (-3)
Risk factors or protective factors	Sel. Prevention (-1)
Subclinical symptoms level or mental health condition onset	Ind. Prevention (+1)
Clinical symptoms level or mental health condition progression	Treatment (+3)
Unclear or insufficient information	NA
O2. How was the considered outcome measured?	
Scale for wellbeing / knowledge and understanding / 'change in attitudes' or similar outcome	Promotion / Univ. Prevention (-3)
Measure of risk profile/level	Sel. Prevention (-1)
Checklist (with or without cut-off) or diagnostic tool to measure subclinical symptoms and/or to determine caseness	Ind. Prevention (+1)
Clinical scale for reduction of clinical symptoms / severity (cut-off)	Treatment (+3)
Unclear or insufficient information	NA

Additional option: NA Unclear or insufficient information. Additional notes: [1] For example, was the study population screened for the presence of a mental condition or indicators and proxies of psychological distress or other mental health condition using a mental health instrument / symptom checklist. [2] Hint: Consider the operationalization of the inclusion and exclusion criteria (if any). [3] Hint: see study sample characteristics, typically reported in Table 1.