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Towards a framework for good outcome in people at clinical high risk for psychosis: A Delphi consensus study

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ABSTRACT

Background: Outcomes in people at clinical high risk for psychosis (CHR—P) have usually been defined in terms of psychosis onset. However, within the subgroup of individuals who do not develop psychosis, some have persistent symptoms; while in others, symptoms resolve and functioning is restored. Currently, little is known about what predicts a good outcome (GO) in CHR-P individuals, partly because there is no consensus on how this should be defined.
Method: The Delphi method was used to elicit the opinions of 46 experts to reach a consensus on factors that together could define GO in the CHR-P population. Three online surveys were implemented. The panel rated each survey item according to how important they thought it was as a measure of GO. Participants also answered open-ended questions on how GO should be determined, their responses were subject to content analysis.
Results: Ninety-eight items were endorsed by 80% of the panel as essential or important for a GO; these fell into 4 domains: Functioning; Symptoms; Distress/Suicidality; and Subjective Wellbeing. The individual item that was rated as the most important, was daily functioning. Themes emerged from the qualitative data, which corresponded to the Delphi domains, including 'functioning'; 'clinical factors; and 'user-defined outcomes'.
Conclusions: A GO in CHR-P subjects can be defined by using a combination of measures from domains that reflect level of functioning; symptoms; distress/suicidality; and subjective wellbeing. These results provide a basis for a standardised definition of good outcome in people at clinical high risk of psychosis.

1. Introduction

Existing literature on individuals at Clinical High Risk for Psychosis (CHR—P) (Fusar-Poli, 2017) is primarily vulnerability- and disease-focused; traditionally attention has centred on transition to psychosis (Yung and Nelson, 2013), comparing individuals who transition with those who do not (Fusar-Poli et al., 2015a) and the risk factors involved (Fusar-Poli et al., 2017c). However, recent evidence suggests that 80% of CHR-P patients do not develop psychosis at 2 years (from eTable 4 in (Fusar-Poli et al., 2016a). These patients are traditionally labelled "false positives", yet such a designation may be partially misleading as it implies that they will all recover. On the contrary, amongst those who do not transition, about two thirds present with persistent attenuated psychotic symptoms (APS) and about half continue to display functional impairment, with only 20% reaching functional and symptomatic remission (Rutigliano et al., 2016). The North American Prodrome Longitudinal Study (NAPLS) revealed that 50% of a non-transitioned sample remitted from APS at follow-up (Addington et al., 2011), whereas a meta-analysis discovered cumulative remission rates of just 35% amongst individuals who meet criteria for CHR-P (Simon et al., 2013). Collectively, the evidence indicates that the CHR-P population may face several negative outcomes beyond transition to psychosis.

Few studies have investigated favourable outcomes in the CHR-P group, e.g. symptomatic remission and functional recovery (Lee et al., 2014a; Schlosser et al., 2012); compared remitters with non-remitters; or examined predictors of good outcomes (GOs) (Lee et al., 2014b). A major obstacle for this research is the lack of a clear operationalisation of a GO and current psychometric tools for examining the CHR-P state, e.g. Comprehensive Assessment of At Risk Mental States (CAARMS) (Yung et al., 2006) or Structured Interview for Psychosis-Risk Syndromes (SIPS) (Miller et al., 2003), do not provide clear criteria for defining GOs. This is further complicated by the fact that the CHR-P group is composed of samples who have been risk-enriched (i.e. help-seeking patients selected from specialised high-risk services, who are therefore at increased risk of psychosis compared to

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individuals from the general population) (Fusar-Poli et al., 2016b; Fusar-Poli et al., 2016c) and are intrinsically heterogeneous (Fusar-Poli et al., 2016a), with differential long-term outcomes (e.g. transition to psychosis (Fusar-Poli et al., 2017a; Fusar-Poli et al., 2015b); remission from or enduring APS (Michel et al., 2017; Simon et al., 2013); functional deterioration or recovery (Cornblatt et al., 2012; Schlosser et al., 2012). Furthermore, the definition of a GO for any psychological disorder is contingent upon the stakeholder's subjective view, much like clinical and personal recovery (Slade and Longden, 2015). Thus, a heuristic definition of GO should include factors beyond symptomatic remission and the perspectives of various stakeholder groups (e.g. service-users, clinicians).

This study aims to develop a preliminary framework for assessing GO in CHR-P individuals who have not transitioned to psychosis, with the intention that the findings will contribute to the future development of a GO tool that can be used in CHR-P research. The study uses the Delphi method, a technique for exploring topics with limited existing evidence and was used to systematically reach consensus amongst clinical experts on indicators that could define short- and long-term (1 and 5 years) GO in the CHR-P population. To our knowledge, this is the first study to develop a CHR-P GO framework, which we expect will be defined by a combination of clinical and functional variables, consistent with the multi-faceted nature of the CHR-P status.

2. Method

2.1. Participants

CHR-P-expert clinicians and researchers ($n = 135$) were identified from the authorlines of publications on clinical outcomes in CHR-P patients. They were invited to participate via email and to share the invitation with colleagues they considered to be fellow CHR-P experts.

2.2. Study procedures

King's College London Research Ethics Committee approved the study. A search of articles published up to October 2017 examining CHR-P outcomes other than transition was conducted using Ovid Medline (see Supplementary Material 1 for search terms). Themes drawn from the literature were used to create a pilot Delphi survey, which was implemented amongst five clinical researchers considered representative of the expert panel. These researchers were invited to participate via email and were based at King's College London at the time, however they had worked at, or collaborated with, various international CHR-P centres and had clinical and research experience with psychosis patients across the spectrum. Pilot data was not included in the final analysis. The final Delphi process involved three successive online surveys implemented using Qualtrics software.

2.2.1. Delphi: Round 1

Round 1 comprised two sections (see Supplementary Material 2 and eFig. 1). In Section 1 participants were asked to select items they considered important as indicators of a GO in CHR-P patients, both in the short- and long-term. The distinction between short- and long-term outcome (1 and 5 years respectively) was considered as the risk of conversion to psychosis in CHR-P individuals rises as follow-up time increases (Fusar-Poli et al., 2012), thus corresponding to the likelihood of a GO. The responses to Section 1 were used to develop the Round 2 survey. Items were excluded if they were not selected by the absolute majority (i.e. ≥50%), consistent with previous Delphi studies (Freitas et al., 2018; von der Gracht, 2012). Section 2 comprised open-ended questions on how protective factors can be modified to encourage GOs in CHR-P individuals; responses were subject to content analysis (see Supplementary Material 4 for content analysis procedure and results).

2.2.2. Delphi: Round 2

Round 2 contained items that survived Round 1, plus additional items suggested by the Round 1 participants (see eFig. 1). Six Likert-type questions were implemented; five involved rating the importance of each item as a potential indicator of GO in CHR-P individuals (1 = Essential; 2 = Important; 3 = Unsure/Depends; 4 = Not Important; 5 = Should not be included). Each question was based on a different timeframe (i.e. long/short-term) or a different perspective (i.e. expert perspective/expert-predicted patient perspective; service-users were not included in the study). Question six involved rating the importance of protective factors that could foster GO (see eTable 1 for results). Participants were encouraged to suggest new items, explain their responses and provide feedback on the questions.

Consistent with previous studies (Byrne and Morrison, 2014; Law and Morrison, 2014), items achieved consensus if rated as 'essential' or 'important' by ≥80% of the panel (Langlands et al., 2008). Items endorsed by 50–79% of the sample were re-introduced in Round 3 to be re-rated (see eFig. 1). Items not meeting these two conditions were excluded.

2.2.3. Delphi: Round 3

Round 2 participants received lists of the 'accepted', 'rejected' and 'to be re-rated' items; for the latter, group medians and ranges were revealed and each participant's own Round 2 responses were provided, to enable comparisons with the group. New items suggested by the Round 2 panel were rated for the first time, only those considered 'essential' or 'important' by ≥80% of the sample were retained (Byrne and Morrison, 2014; Law and Morrison, 2014).

3. Results

Forty-six CHR-P experts participated in Round 1 (34.1% response rate), 39 in Round 2 (84.7%) and 30 in Round 3 (76.9%) (see Table 1). The sample were representative of the target group and there was no difference in demographics, profession or experience between those who were contacted and did participate and those who did not.

3.1. Delphi process

Of the 73 Round 1 items, 46 were endorsed by >50% of the sample, and 42 were excluded (see Fig. 1). Seventy-two new items were introduced by the panel, thus 137 items were implemented in Round 2 (divided up by 6 questions – see Supplementary Material 2). Eighty-six items achieved consensus in Round 2 and 48 were re-rated in Round 3. The Delphi process produced 98 items that achieved consensus (>80%) (see Supplementary Material 3), these were categorised according to time-point (1 or 5 years) and perspective (expert or expert-predicted patient perspective - see Supplementary Materials 2, 3 and Tables 2 & 3). Some items were endorsed by fewer participants as they were introduced later in the Delphi process (when the sample was smaller).

Four domains emerged from the Delphi data: 1) Functioning, 2) Symptoms; 3) Distress/Suicidality; and Subjective Wellbeing. Within these domains, there were 15 indicators (from the experts' perspective) of GO at 1 year and 15 at 5 years (see Table 2). Seventeen indicators of GO at 1 year and 13 at 5 years emerged as what the experts perceived as the service-users' perspective (see Table 3). Overlap existed between items endorsed by the experts and those they believed to be important to patients, and between items considered important at 1 and 5 years. Good daily functioning was regarded the most important indicator of GO at 1 (100% endorsement) and 5 years, irrespective of the viewpoint considered. Self-reported improvement in mental health received 100% endorsement as an indicator of GO at 1 year. Functioning, reduction in distress and factors relating to subjective wellbeing, were rated higher than APS improvement and remission, although improvement was rated important at 5 years. Absence and amelioration of negative

Table 1
Round 1 Participant Characteristics.

Variable	N=46
Continents represented	*Europe* (*n* = 30); *N. America* (*n* = 8); *Australia* (*n* = 4); *Asia & Middle East* (*n* = 3); *S. America* (*n* = 1)
Specialty of panelists	*Psychiatrists* (*n* = 20); *psychologists* (*n* = 17); *researchers/lecturers* (*n* = 8); *social workers* (*n* = 1)
No. of years working with CHR-P individuals	*10+ (48%)*
Type of experience ***(multiple responses permitted)***	*Researcher recruitment* (*n* = 34); *principal investigator* (*n* = 28); *manual/protocol development* (*n* = 26); *medical practitioner/clinician* (*n* = 24); *instrument/assessment development* (*n* = 23); *psychological intervention* (*n* = 21); *trial coordination* (*n* = 14). *Less common types of experience included*: *n* = 4: *psycho-pharmacology*; *clinical lead/director of early detection service*; *secondary data analysis*
Field of CHR-P research ***(multiple responses permitted)***	*Early detection, prevention and intervention* (*n* = 33); *neuroimaging* (*n* = 20); *psychological intervention* (*n* = 16); *pathophysiology, neurochemistry and genetics* (*n* = 16); *recovery* (*n* = 6); *psychopharmacology* (*n* = 4); *environmental risk factors* (*n* = 3)
Employment setting ***(multiple responses permitted)***	*University/research centre* (*n* = 41); *hospital* (*n* = 9) *and community/outpatient clinic* (*n* = 8); *CBT training centre* (*n* = 1)
Routinely used CHR-P tools ***(multiple responses permitted, n = 34 reported using at least 2 instruments)***	*CAARMS* (*n* = 31); *SIPS/Scale of Prodromal Symptoms* (*n* = 16); *Brief Psychiatric Rating Scale* (*n* = 12); *Schizophrenia Proneness Instrument*; *Adult/Child and Youth version* (*n* = 11); *Prodromal Questionnaire* (*PQ-16*); *Basel Screening Instrument for Psychosis* (*n* = 1); *Early Recognition Inventory based on Interview for the Retrospective Assessment of the Onset of Schizophrenia* (*n* = 1)

symptoms at 1 year were considered highly important from the experts' perspective. Participants rated the importance of various protective factors that could foster GO in CHR-P individuals, these are shown in eTable 1.

3.2. Content analysis

The Round 1 qualitative data produced 111 codes, which were translated into 14 categories; five themes emerged that traversed the Delphi domains: 'functioning'; 'clinical factors'; 'user-defined outcomes'; 'assessment and research'; and 'support' (see Supplementary Material 4 for analysis of the major theme 'support').

4. Discussion

The current findings are in line with calls to extend the focus of CHR-P research beyond vulnerability to psychosis, and to assess clinical outcome in terms that are broader than transition to psychosis (Michel et al., 2017; Schlosser et al., 2012; Simon et al., 2013). The Delphi method was used to elucidate the opinions of clinical and academic experts on indicators that could define a GO in the CHR-P samples. A high degree of consensus (≥80%) emerged on such indicators, both in the short- and long-term, which belong to four GO domains: (i) functioning, (ii) symptoms, (iii) distress/suicidality and (iv) subjective wellbeing.

Good daily functioning was considered fundamental to a GO, both at 1- and 5-years, irrespective of the viewpoint considered (patient/expert-predicted patient perspective) and consistent with the evidence that functioning can indicate outcome in CHR-P subjects better than symptom severity or frequency (Brandizzi et al., 2015; Carrion et al., 2013; Lin et al., 2011). Although the panel also rated social functioning (i.e. ability to engage in social interactions/interpersonal relationships) and role functioning (i.e. ability to perform occupational/family/household duties) as important GO measures, daily functioning (or activities of daily living), which pertains to self-care (e.g. bathing, self-feeding) and living independently (e.g. managing finances, household chores) (Mlinac and Feng, 2016), was considered more important. While the former are frequently assessed in CHR-P subjects, daily functioning is not evaluated in a standardised way, despite evidence of its relationship with negative and depressive symptoms (Dominguez-Martinez et al., 2015). The results of this study suggest that future investigations should also consider a very basic level of functioning, which can be overlooked in young patients who are less recognisably disabled. Surprisingly, good neurocognitive functioning, which has been linked to poor long-term functioning (Lin et al., 2011), did not reach consensus as an indicator of GO at 1 or 5 years. However, experts reported that the would consider a patient's cognitive abilities, when evaluating GO in general (see Supplementary Material 3).

The GO indicators experts perceived as meaningful to patients included more symptom-related factors e.g. amelioration/absence of presenting complaint, than those they identified as important from their perspective, however, absence of negative symptoms was regarded as important both at 1 and 5 years. Few studies have explicitly investigated negative symptoms in CHR-P patients, but they have been linked to poor short- and long-term outcomes (Carrion et al., 2013; Salokangas et al., 2014). Regarding positive symptoms, the qualitative data revealed that many of the panel believe there is a need for "criteria for complete remission" of APS, especially when considering long-term outcome. They also suggested a minimum time-period for remission from APS be defined, "like the 5-year survival period usually employed in oncology". The risk for psychosis in CHR-P patients peaks within the first 2–3 years and then plateus (Kempton et al., 2015), thus a 3-year remission period may be appropriate for this group. Future CHR-P investigations should aim to include a ≥3-year follow-up and implement repeated assessments to avoid mislabelling individuals, particularly when symptoms and functioning are likely to ebb and flow.

Lack of distress associated with APS was considered essential to a GO in CHR-P patients (>90% consensus on included items) both in the short- and long-term, and regardless of the perspective considered. This is consistent with evidence that CHR-P clients often seek clinical help because of the distress associated with their symptoms (Falkenberg et al., 2015). Furthermore, there is consensus that distress is an essential criterion to define clinically meaningful APS (Fusar-Poli et al., 2017b) in the context of CHR-P research. Suicidality was deemed important to a good short-term outcome, consistent with evidence that suicide risk is high in this subgroup (Taylor et al., 2015).

The largest domain emerging from the Delphi process was 'subjective wellbeing', which included personally meaningful, user-defined indicators of a GO (e.g. stress coping, achievement of personalised goals), which are typically seen as features of 'recovery' (Jacob, 2015), a concept developed for patients with psychotic disorders (Slade and Hayward, 2007), rather than CHR-P individuals. 'Recovery' from established psychosis implies that an individual leads a satisfying life despite the limitations caused by their enduring illness (Anthony, 1993). One expert stated that "for those with a psychotic illness, a GO depends on the seriousness of symptoms and making a good recovery, whereas for CHR-P they would want to be functioning normally". Thus, the threshold for 'recovery' may be higher in CHR-P subjects than in those with psychosis.

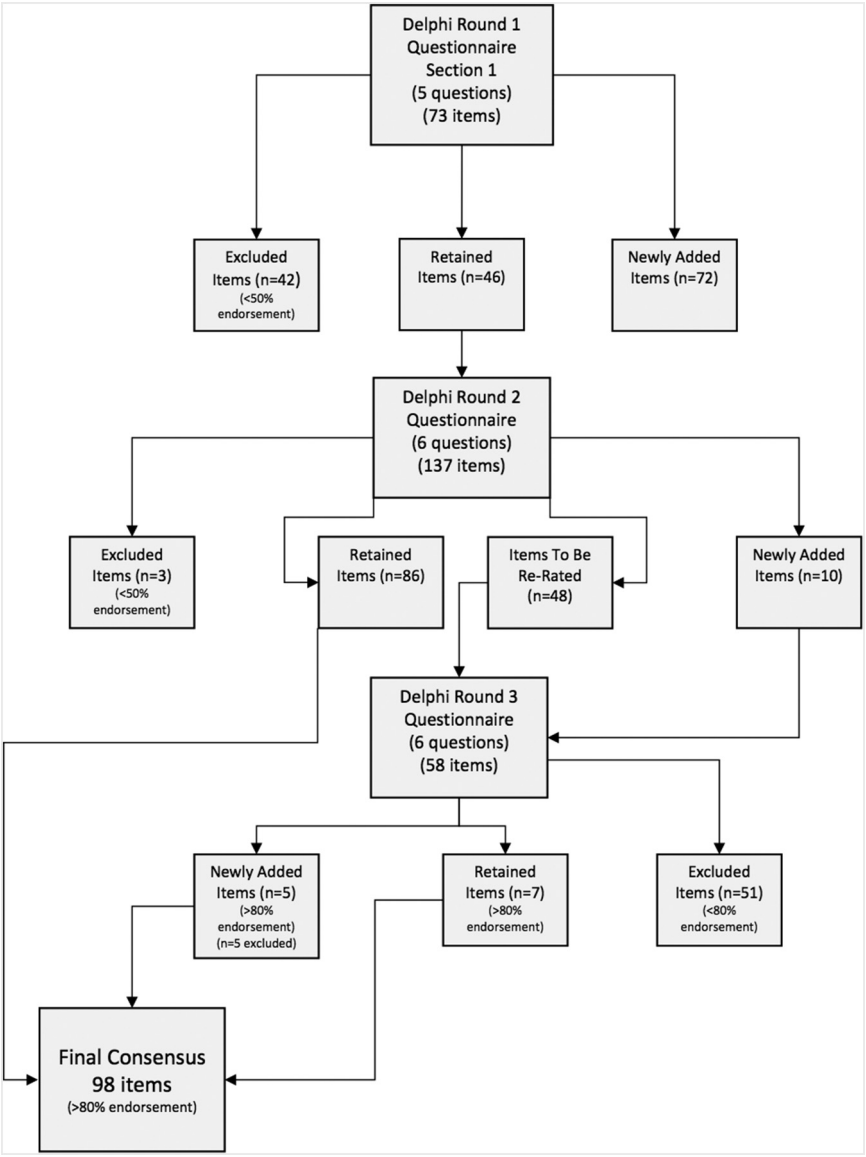

Fig. 1. Flow Diagram of Retained, Excluded and Re-rated Items During the Delphi Process.

4.1. Framework for GO

Based upon these results, GO in CHR-P subjects who have not developed psychosis could be defined in terms of the following domains and items:

1) ***Functioning:*** good daily functioning; good social and role functioning (employed/studying); presence of supportive social network.
2) ***Symptoms:*** amelioration/absence of positive and negative symptoms; absence of co-morbid mental disorder/s; improvement/absence of presenting complaint/s.
3) ***Distress/Suicidality:*** absence/reduction of distress associated with symptoms; absence of suicidal ideation.
4) ***Subjective Wellbeing:*** subjective improvement in mental health; achievement of personal goals; good subjective quality of life; improved tolerance to stress.

4.2. Recommendations for the Assessment of GO

The framework described above provides a foundation for the main objective of the study; to contribute towards the future development of a tool to assess GO in CHR-P individuals. In the interim, we have made some preliminary suggestions assessing GO status (see Table 4), following the approach used for assessesing treatment effectiveness in patients with schizophrenia (Juckel et al., 2014). It is important to note that the following recommendations are centred on the study findings, yet not specifically drawn from suggestions made by our sample.

4.2.1. Functioning

Functioning assessments should be completed 3-monthly, as CHR-P status is not defined by symptoms alone (Yung et al., 2006). We suggest that the Life Skills Profile-16 (abbreviated LSP-39 (Rosen et al., 1989) is used to assess daily functioning, until a CHR-P-specific measure of daily functioning is established; LSP was developed to assess community adaptation in schizophrenic patients (Rosen et al., 1989) and has successfully been implemented on first episode psychosis samples (Raghavan et al., 2017). Social and role functioning can be determined using standardised measures (e.g. Global Functioning(GF):Social scale (Auther et al., 2006); GF:Role scale (Niendam et al., 2006.); Social and Occupational Functioning Assessment Scale (SOFAS) (Goldman et al., 1992). The Global Assessment of Functioning (GAF) Scale (Hall, 1995) may be considered, however GAF scores often reflect symptom severity as opposed to functional impairment per se. Measurement of perceived social support (e.g. using the Multidimensional Scale of Perceived Social

Table 2
Indicators of Good Outcome in CHR-P Individuals: Expert Perspective (≥80% endorsement by panel, *n*=38).

Functioning (%)	Symptoms (%)	Distress/Suicidality (%)	Subjective wellbeing (%)
Good Outcome at 1 Year			
Good daily functioning (100)	No psychotic disorder (86.8)	Reduction in distress associated with attenuated psychotic symptoms (92.1)	*Subjective improvement in mental health (100)*
High social functioning (89.5)	Amelioration of negative symptoms (86.8)	Risk of suicide (92.1)	Reduction in subjective distress (94.7)
Employed or studying (86.8)	Absence of negative symptoms (84.2)		Subjective good quality of life (89.5)
			Subjective improvement in coping (86.8)
			Achievement of goals (84.2)
			Restored tolerance to stress (84.2)
			Sense of autonomy (83.3)
Good Outcome at 5 Years			
Good daily functioning (97.4)	No psychotic disorder (89.5)	Reduction in distress associated with attenuated psychotic symptoms (89.5)	Subjective improvement in mental health (94.7)
High social functioning (89.5)	Amelioration of negative symptoms (89.5)		Reduction in subjective distress (86.8)
Employed or studying (89.5)	Absence of negative symptoms (84.2)		Achievement of goals (86.8)
	Amelioration of attenuated psychotic symptoms (84.2)		Restored tolerance to stress (86.8)
			Supportive social network (84.2)
			Subjective improvement in coping (81.6)
			Better understanding of psychosocial context of attenuated psychotic symptoms (81.6)

Support (MSPSS) (Zimet et al., 1988), can ensure inclusion of individuals who feel unsupported despite being socially integrated.

4.2.2. Symptoms

Comorbid psychological disorders should be assessed 6-monthly using the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I) (First et al., 1995) and APS and negative symptoms assessed more frequently (3-monthly) using the CAARMS (Yung et al., 2006). The latter could also be assessed using the Scale for the Assessment of Negative Symptoms (SANS) (Andreasen, 1989). Close measurement of symptom course and progression can quickly indicate psychosis transition, similar methods have been utilised in previous longitudinal CHR-P

Table 3
Indicators of Good Outcome in CHR-P Individuals: Expert-Predicted Patient Perspective (≥80% endorsement).

Functioning (%) (n)	Symptoms (%) (n)	Distress/Suicidality (%) (n)	Subjective wellbeing (%) (n)
Good Outcome at 1 Year			
Good daily functioning (97.3) (37)	Amelioration of presenting complaint (89.2) (37)	Lack of distress associated with attenuated psychotic symptoms (94.6) (37)	Achievement of goals (86.5) (37)
High social functioning (89.2) (37)	Absence of presenting complaint (86.8) (38)	Absence of suicidal ideation (86.7) (30)	Satisfaction in range of life areas (86.5) (37)
Employed or studying (86.5) (37)	No psychotic disorder (84.2) (38)		Living life as desired/freedom (83.8) (37)
	No co-morbid mental disorder/s (81.6) (38)		Feeling of mastery (86.7) (30)
	Amelioration of attenuated psychotic symptoms (81.1) (37)		Supportive social network (86.5) (37)
			Better coping strategies (86.5) (37)
			Improved tolerance to stress (83.8) (37)
Good Outcome at 5 Years			
Good daily functioning (97.4) (36)	Improvement of presenting complaint (89.5) (36)	Lack of distress associated with attenuated psychotic symptoms (94.7) (36)	Achievement of personalised goals (89.5) (36)
High social functioning (89.5) (36)	Lack of development of psychotic disorder/s (86.8) (36)		Improved effective coping strategies (89.5) (36)
Successfully employed or studying (89.5) (36)	Absence of presenting complaint/s (84.2) (36)		Improved tolerance to stress (86.8) (36)
			Living life as they would like/freedom (86.8) (36)
			High satisfaction in a wide range of life areas (84.2) (36)
			Satisfactory supportive social network (84.2) (36)

Table 4
Recommended Domains and Scales for the Assessment of Good Outcome in CHR-P Individuals.

Good Outcome in CHR-P

Functioning – 3 Monthly Assessments

- **Daily Functioning**
  LSP (Rosen et al., 1989)
- **Social Functioning**
  GF: Social (Auther et al., 2006) - score of 7>
  SOFAS (Goldman et al., 1992) - score of 71> [a]
- **Role Functioning**
  GF: Role (Niendam et al., 2006)
- **Employed/Studying**
  Dichotomous rating of employment or study status (full- or part-time)
- **Presence of Supportive Social Network**
  MSPSS Scale (Zimet et al., 1988) - higher total score = higher perceived support

Symptoms – 3 Monthly Assessments

- **Positive Symptoms**
  CAARMS (Yung et al., 2006) APS Module
  Amelioration - APS have met CHR-P severity criteria but not frequency (Woods et al., 2014)
  Absence - severity score ≤2 (mild) [a, b]
- **Absence of Co-morbid Mental Disorder/s**
  SCID-I (First et al, 1995)
  Not meeting criteria for any Axis I disorder - *6 monthly assessments*
- **Negative Symptoms**
  CAARMS (Yung et al., 2006) Negative Symptoms Module
  Amelioration - severity criteria reduced by 1 score
  Absence - severity score ≤2 (mild) [b]
  OR
  SANS (Andreasen, 1983)
  Absence - total score reduction

Distress/Suicidality – 3 Monthly

- **Absence of Suicidal Ideation** [c]
  C-SSRS (Posner et al., 2011) - previous self-harm/suicidal attempts factored into level of risk
- **Absence of Distress Associated with Symptoms**
  CAARMS (Yung et al., 2006) APS module - scale for distress associated with symptoms

Subjective Wellbeing – 3 Monthly Assessments

- **Subjective Improvement in Mental Health**
  WEMWBS (Tennant et al., 2007) - higher total score = higher wellbeing
- **Subjective Quality of Life**
  MANSA (Priebe et al., 1999) - higher total score = higher perceived quality of life
- **Improved Tolerance to Stress**
  PSS (Cohen et al., 1983) - scores ranging from 0-13 considered as low stress
  OR
  Brief COPE (Carver, 1997) - no total score, 14 coping style scales with scores ranging 2-4, higher score = increased use of coping strategy
- **Achievement of Personal Goals**
  Actual achievement of set goals

[a] *For individuals with genetic risk for psychosis (and present with low threshold symptoms), functioning should return to 90% of previous best SOFAS score similar to Addington et al., 2015*
[b] *A stable period of 6 months is required for individuals to meet full remission*
[c] *Can be assessed more frequently if patient presents high risk to self with multiple previous suicide/self-harm attempts*

studies (Morrison et al., 2011; van der Gaag et al., 2012). Woods et al. (2014) have proposed a set of criteria for APS amelioration and remission using the SIPS, however we recommend the CAARMS, as 69% of our sample reported using this tool routinely within their clinical and research activities. Symptomatic improvement or partial remission (Woods et al.) can be observed even if patients continue to meet severity criteria for being at-risk (i.e. score of ≥3) but not frequency (i.e. score of ≤2). Full remission requires mild positive symptoms (score of ≤2) and a frequency score of ≤2. As per Woods et al., we suggest a stable period of six months for partial or full APS remission. Negative symptoms are not prioritised in CHR-P patients and are less well-researched; however, based upon our findings, we recommend standard routine assessment of negative symptoms. We further propose the same criteria for full remission of negative symptoms as APS, with a reduced severity score of 1 for amelioration, since there are no status cut-offs defined, as there are for APS (i.e. CHR-P status).

4.2.3. Distress/Suicidality

We recommend 3-monthly assessments of suicidality, which could be measured using the Columbia Suicide Severity Rating Scale (C-SSRS) (Posner et al., 2011) (factoring in previous self-harm/suicidal attempts into level of risk), and the same for distress associated with APS. The latter can be assessed whilst implementing the CAARMS (Yung et al., 2006), as patients rate their distress on a scale of 0–100 for the most prominent symptoms falling within the four APS module domains (unusual thought content; non-bizarre ideas; perceptual abnormalities; disorganised speech). Patients may report distress associated with multiple APS, thus the clinician must assess whether it is clinically meaningful to monitor the highest distress rating reported. Due to differences in resilience levels between patients, it is difficult to objectively set a cut-off score for a reduction in distress.

4.2.4. Subjective Wellbeing

Subjective wellbeing; quality of life; perceived stress; and stress tolerance, can be assessed 3-monthly using the Warwick-Edinburgh Mental Well-being scale (WEMWBS) (Tennant et al., 2007); Manchester Short Assessment of Quality of Life (MANSA) (Priebe et al., 1999); Perceived Stress Scale (PSS) (Cohen et al., 1983); and Brief COPE (Carver, 1997), respectively. All have successfully demonstrated validity and reliability in CHR-P patients, however no defined cut-off scores exist as these measures are not intended for diagnostic use. Personal goals can be established at baseline and achievement can be subsequently reviewed.

A major limitation of this study is the absence of service-user perspectives and a contrast of opinions from both clinical- and patient-experts, thus, framework that incorporates views from two major stakeholders. Therefore, we are implementing a concurrent analogous study, focusing on what is meaningful to CHR-P service-users, which will contribute to the future development of a GO tool for this clinical group. A further limitation concerning the sample relates to the limited representation of researchers from North America, Australia and Asia, which are home to several major CHR-P research centres. Including a predominantly European expert panel could have restricted the cultural diversity of the GO framework and could lead to the development of a tool that is tailored towards specific healthcare systems and interpretations of wellbeing.

Although the sample size was modest, each Delphi round achieved a high response rate, indicating the importance of the topic. There are a

limited number of existing Delphi studies in psychosis research. However, we briefly compared the quality of the current study to four well-cited psychosis Delphi studies (Addington et al., 2013; Fiander and Burns, 1998; Langlands et al., 2008; Marshall et al., 2004) (see Supplementary Material 5), and found the mean sample size was $n = 29$; smaller than the current panel of experts. Furthermore, the study with the largest sample of clinical experts (Langlands et al., 2008) received lower response rates for Round 2 (79%) and Round 3 (62%) in comparison to the present study. For many items included in the current study, consensus was reached by the second round, with only minor changes to item scores between Rounds 2 and 3, suggesting that participant views were relatively robust and not greatly altered by differing opinions from other experts. The panel added their own comments throughout the Delphi process, permitting the development of new items and ensuring that unforeseen GO indicators were not overlooked. However, as descriptions were not provided for the items listed, there may have been some variability in how these were interpreted by the experts, which could have affected the ratings.

Overall, this study provides consensus-based evidence that outcomes in CHR-P subjects need to be assessed in terms beyond the simple binary categorisation of the onset (or non-onset) of psychosis. It provides a preliminary framework for the operationalisation of a GO in this population in terms of domains relating to functioning, symptoms, distress/suicidality and subjective wellbeing, with each domain comprising multiple factors. As indicated in Table 4, these factors should be considered and assessed separately, to accurately measure the high inter-individual variability of a GO. The high variance in clinical outcomes within CHR-P individuals (Rutigliano et al., 2016) is likely due to the accumulation of different risk or protective factors for psychosis in these samples (Fusar-Poli et al., 2017c; Radua et al., 2018). Our comprehensive and pragmatic definition of GO may capture the impact of these different risk or protective factors on the individual trajectory from an initial CHR-P stage. For example, the measures of GO that we propose can be applied to all CHR-P patients, regardless of disease stage (Fusar-Poli et al., 2017a) or subgroup i.e. APS/brief and limited intermittent psychotic symptoms (BLIPS)/genetic risk (Yung et al., 2005). Similarly, the findings could be used to standardise assessments within clinical and epidemiological CHR-P research, and to refine clinical prediction modelling. Another potential application is to inform future randomised controlled trials in the CHR-P population, which are urgently needed, given the lack of effective clinical interventions at present (Davies et al., 2018). A reliable GO tool could be used in future trials to standardise the assessment of the potential impact of preventive interventions on outcomes other than psychosis. Furthermore, a pragmatic view is that any instrument for assessing a GO can be easily and speedily implemented in a clinical setting. At present, we are lacking established CHR-P-specific measures designed to assess some of the factors listed in our GO framework, for example, measures of daily functioning e.g. LSP (Rosen et al., 1989) have rarely been used on CHR-P subjects. However, there is consensus that the assessment of daily functioning is essential to GO, thus this should encourage the development of future validity and reliability studies of such measures.

The next phase of this research will enable further development of our model into one that incorporates multi-vocal perspectives, allowing us to produce a robust tool for GO in the CHR-P group. To support our current data, we plan to implement the present GO framework as an outcome measure in a longitudinal CHR-P study to assess its reliability.

5. Conclusion

There is no single measure that can be used to define a GO in CHR-P subjects; rather, this should be defined in terms of domains relating to functioning, symptoms, distress/suicidality and subjective wellbeing, and based upon the perspectives of both the clinicians' and the patients. Our findings echo calls to expand the assessment of outcomes in individuals at CHR-P beyond vulnerability to psychosis to include good as well as adverse outcomes.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.schres.2019.02.019.

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Contributors

NP carried out the Delphi procedure with the participants, conducted the analysis and wrote the draft manuscript. Analysis of the qualitative data was carried out jointly by NP, ER and SV. All authors were involved in design of the study and revised and approved the final version of the manuscript.

Conflicts of interest

All authors declare they have no conflict of interest.

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